

US3342200 (Prod: Tekton Research- Austin)

Generated By: (b) (6)

Generated On: 26 Nov 2020 11:00:19

All time stamps listed in this document are displayed in GMT

**US3342200**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 11:00:19**

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[Participant ID](#)

US3342200

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

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US3342200

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:00:19

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 11:00:19

Date of Birth (MMM yyyy)	(b) (6) 1975
Age	44
Age Units	YEARS
Age (Derived)	44
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:00:19

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 11:00:19

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:00:19

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:00:19

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	12 NOV 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	12 NOV 2018
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2018
Start Year (derived)	2018
Stop Month and Year (derived)	NOV 2018
Stop Year (derived)	2018



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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:00:19

Condition	PRECANCEROUS CERVICAL CELLS
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	12 NOV 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	NOV 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:00:19

Condition	KIDNEY STONES
Start date (dd MMM yyyy)	UN UNK 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)	UN UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:00:19

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1993
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 1993
Start Year (derived)	1993
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:00:19

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

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:00:19

Condition	LATEX ALLERGY - HIVES
Start date (dd MMM yyyy)	UN UNK 1993
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 1993
Start Year (derived)	1993
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:00:19

Condition	VITAMIN D DEFICIENCY
Start date (dd MMM yyyy)	UN UNK 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)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:00:19

Condition	JOINT PAIN BILATERAL SHOULDERS
Start date (dd MMM yyyy)	UN MAY 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:00:19

Condition	BILATERAL PAIN BILATERAL LOWER EXTREMITIES
Start date (dd MMM yyyy)	UN UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:00:19

Condition	RIGHT BREAST LUMP BENIGN
Start date (dd MMM yyyy)	UN AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN AUG 2020
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	AUG 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:00:19

Condition	RIGHT BREAST LUMP BIOPSY
Start date (dd MMM yyyy)	UN AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN AUG 2020
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	AUG 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:19

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> )	15:59 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 15:59
Height ( <i>xxx.x</i> )	163.5 cm
Weight ( <i>xxx.x</i> )	065.4 kg
BMI ( <i>xxx.x</i> )	24.46483 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 11:00:19

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: Childbearing Potential

Generated On: 26 Nov 2020 11:00:19

Date of assessment ( <i>dd MMM yyyy</i> )	4 SEP 2020
Is the participant of childbearing potential?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If No, what is the reason?	Surgically sterile <input checked="" type="radio"/>
	Post-menopausal <input type="radio"/>
	Partner medically sterile <input type="radio"/>
	Not reached age of Menarche <input type="radio"/>
	Other <input type="radio"/>
If Partner medically sterile or Other, specify _____	
If Surgically sterile, date of surgery ( <i>dd MMM yyyy</i> )	12 NOV 2018
Date of surgery unknown	False
If Post-menopausal, date of last menstruation ( <i>dd MMM yyyy</i> ) _____	
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:19

**Occupational Risk**

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

**Specify**

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

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:19

<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 11:00:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 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 11:00:19

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

What was the participant's randomization number? 111836

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 11:00:19**

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 11:00:19

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)	15:59 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 15:59
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 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 11:00:19

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)	17:21 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 17:21
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:19

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 11:00:19

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	4 SEP 2020
What was the treatment time? (00:00-23:59)	16:51 (24 HR)
Treatment Date and Time (derived)	4 SEP 2020 16:51
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:19

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> )	16:24 (24 HR)
Collection date and time (derived)	4 SEP 2020 16:24

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:00:19

Collection date ( <i>dd MMM yyyy</i> )			4 SEP 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:25	4 SEP 2020 16:25
Nasopharyngeal Swab 2	No		



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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:00:19

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 11:00:19

**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

98.7 °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

04 SEP 2020 17:22

PC Open Date & Time

04 SEP 2020 17:11

PC Close Date & Time

04 SEP 2020 19:41

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 11:00:19

**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 98.4 °F

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

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

PC Time Stamp	04 SEP 2020 20:40
PC Open Date & Time	04 SEP 2020 20:36
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 11:00:19

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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

97.8 °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 12:02

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 11:00:19

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.6 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

06 SEP 2020 18:35

---

PC Open Date & Time

06 SEP 2020 12:00

---

PC Close Date & Time

07 SEP 2020 11:59

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US3342200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:00:19

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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

98.7 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

07 SEP 2020 18:23

---

PC Open Date & Time

07 SEP 2020 12:00

---

PC Close Date & Time

08 SEP 2020 11:59

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US3342200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 11:00:19

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 03:17

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

09 SEP 2020 14:29

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59



US3342200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 11:00:19

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 12:20

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:00:19

**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 17:23

PC Open Date & Time

04 SEP 2020 17:11

PC Close Date & Time

04 SEP 2020 19:41

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 11:00:19

**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 20:40

PC Open Date & Time

04 SEP 2020 20:36

PC Close Date & Time

05 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:00:19

**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 12:02

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 11:00:19

**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 18:36

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:00:19

**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 18:23

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:00:19

**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

09 SEP 2020 03:17

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:00:19

**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 14:29

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59



US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:00:19

**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 12:20

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:00:19

**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 ☐

US3342200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:00:19

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 17:24
PC Open Date & Time	04 SEP 2020 17:11
PC Close Date & Time	04 SEP 2020 19:41

US3342200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:00:19

**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 ☐

US3342200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:00:19

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 20:41
PC Open Date & Time	04 SEP 2020 20:36
PC Close Date & Time	05 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:00:19

**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 ☒

US3342200

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:00:19

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

US3342200

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:00:19

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 ☒



US3342200

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:00:19

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 18:37
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:00:19

**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 ☒

US3342200

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:00:19

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 18:24
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:00:19

**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 ☒

US3342200

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:00:19

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 03:18
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:00:19

**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 ☒

US3342200

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:00:19

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 14:30
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3342200

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:00:19

**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 ☒



US3342200

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:00:19

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 12:21
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3342200

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:19

Was Contact Attempted?

Yes ☒

No ☐

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

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342200

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342200

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:19

Was Contact Attempted?

Yes ☒

No ☐

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

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342200

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342200

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:19

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*

US3342200

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342200

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:00:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2



US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:19

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)	30 SEP 2020
Time of assessment (00:00-23:59)	10:20 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 10:20
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:19

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)	30 SEP 2020
Time of assessment (00:00-23:59)	11:32 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 11:32
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3342200

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3342200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:19

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	30 SEP 2020
What was the treatment time? (00:00-23:59)	10:59 (24 HR)
Treatment Date and Time (derived)	30 SEP 2020 10:59
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3342200

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	30 SEP 2020
Collection time ( <i>00:00-23:59</i> )	10:48 (24 HR)
Collection date and time (derived)	30 SEP 2020 10:48

US3342200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:00:19

Collection date (dd MMM yyyy)			30 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:50	30 SEP 2020 10:50
Nasopharyngeal Swab 2	No		

US3342200

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:00:19

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**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

99.1 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

30 SEP 2020 11:37

---

PC Open Date & Time

30 SEP 2020 11:19

---

PC Close Date & Time

30 SEP 2020 13:49

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US3342200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 11:00:19

**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 98.6 °F

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

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

PC Time Stamp	01 OCT 2020 06:41
PC Open Date & Time	30 SEP 2020 14:44
PC Close Date & Time	01 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 11:00:19

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**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.7 °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

01 OCT 2020 12:00

---

PC Open Date & Time

01 OCT 2020 12:00

---

PC Close Date & Time

02 OCT 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 11:00:19

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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

98.0 °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

02 OCT 2020 12:03

---

PC Open Date & Time

02 OCT 2020 12:00

---

PC Close Date & Time

03 OCT 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:00:19

**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

98.7 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

04 OCT 2020 07:02

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 11:00:19

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.1 °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 12:34

---

PC Open Date & Time

04 OCT 2020 12:00

---

PC Close Date & Time

05 OCT 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:00:19

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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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 02:34

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 11:00:19

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**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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 04:29

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:00:19

**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

30 SEP 2020 11:38

PC Open Date & Time

30 SEP 2020 11:19

PC Close Date & Time

30 SEP 2020 13:49



US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 11:00:19

**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 06:41

PC Open Date & Time

30 SEP 2020 14:44

PC Close Date & Time

01 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:00:19

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 12:01

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 11:00:19

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 12:03

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:00:19

**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 07:03

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:00:19

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 12:34

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:00:19

**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 02:36

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:00:19

**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

07 OCT 2020 04:29

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:00:19

**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 ☐



US3342200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:00:19

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 11:43
PC Open Date & Time	30 SEP 2020 11:19
PC Close Date & Time	30 SEP 2020 13:49

US3342200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:00:19

**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 ☐

US3342200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:00:19

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 06:42
PC Open Date & Time	30 SEP 2020 14:44
PC Close Date & Time	01 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:00:19

**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 ☒

US3342200

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:00:19

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

US3342200

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:00:19

**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 ☒

US3342200

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:00:19

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 12:04
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:00:19

**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 ☒



US3342200

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:00:19

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 07:04
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:00:19

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 ☒

US3342200

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:00:19

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 12:35
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:00:19

**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 ☒

US3342200

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:00:19

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 02:37
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:00:19

**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 ☒

US3342200

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:00:19

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 04:30
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp 07 OCT 2020 16:48

PC Open Date & Time 07 OCT 2020 12:00

---

PC Close Date & Time 08 OCT 2020 11:59

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US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

---

PC Time Stamp 08 OCT 2020 12:00

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(10)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

09 OCT 2020 12:14

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(11)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 11

Select one response below to indicate the intensity of your

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

---

PC Time Stamp 10 OCT 2020 12:04

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(12)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 12

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp 11 OCT 2020 17:26

PC Open Date & Time 11 OCT 2020 12:00

PC Close Date & Time 12 OCT 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(13)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 13

Select one response below to indicate the intensity of your

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

---

PC Time Stamp 12 OCT 2020 16:02

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

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US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(14)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 14

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

---

PC Time Stamp

14 OCT 2020 06:26

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(15)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 15

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp 14 OCT 2020 13:40

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(16)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 16

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

16 OCT 2020 02:16

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

---



US3342200

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(17)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 17

Select one response below to indicate the intensity of your

None ☒

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp 16 OCT 2020 12:08

PC Open Date & Time 16 OCT 2020 12:00

PC Close Date & Time 17 OCT 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 26 Nov 2020 11:00:19

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 07 OCT 2020 16:48

PC Open Date & Time 07 OCT 2020 12:00

PC Close Date & Time 08 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(9)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

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PC Time stamp	08 OCT 2020 12:00
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PC Open Date & Time	08 OCT 2020 12:00
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PC Close Date & Time	09 OCT 2020 11:59
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US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(10)

Generated On: 26 Nov 2020 11:00:19

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 09 OCT 2020 12:15

PC Open Date & Time 09 OCT 2020 12:00

PC Close Date & Time 10 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(11)

Generated On: 26 Nov 2020 11:00:19

**TIMEPOINT**

DAY 11

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 10 OCT 2020 12:04

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(12)

Generated On: 26 Nov 2020 11:00:19

**TIMEPOINT**

DAY 12

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 11 OCT 2020 17:26

PC Open Date & Time 11 OCT 2020 12:00

PC Close Date & Time 12 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(13)

Generated On: 26 Nov 2020 11:00:19

**TIMEPOINT**

DAY 13

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 12 OCT 2020 16:02

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(14)

Generated On: 26 Nov 2020 11:00:19

**TIMEPOINT**

DAY 14

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 14 OCT 2020 06:26

PC Open Date & Time 13 OCT 2020 12:00

PC Close Date & Time 14 OCT 2020 11:59



US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(15)

Generated On: 26 Nov 2020 11:00:19

**TIMEPOINT**

DAY 15

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 14 OCT 2020 13:40

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(16)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 16

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp 16 OCT 2020 02:16

PC Open Date & Time 15 OCT 2020 12:00

PC Close Date & Time 16 OCT 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(17)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 17

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

**ACHES ALL OVER BODY**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp 16 OCT 2020 12:08

PC Open Date & Time 16 OCT 2020 12:00

PC Close Date & Time 17 OCT 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 26 Nov 2020 11:00:19

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 07 OCT 2020 16:48

PC Open Date & Time 07 OCT 2020 12:00

PC Close Date & Time 08 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(9)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

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PC Time stamp	08 OCT 2020 12:00
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PC Open Date & Time	08 OCT 2020 12:00
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PC Close Date & Time	09 OCT 2020 11:59
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US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(10)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

---

PC Time stamp 09 OCT 2020 12:15

PC Open Date & Time 09 OCT 2020 12:00

PC Close Date & Time 10 OCT 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(11)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 11

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

---

PC Time stamp 10 OCT 2020 12:04

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(12)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 12

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

---

PC Time stamp 11 OCT 2020 17:26

PC Open Date & Time 11 OCT 2020 12:00

PC Close Date & Time 12 OCT 2020 11:59

---



US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(13)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 13

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

---

PC Time stamp 12 OCT 2020 16:02

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(14)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 14

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

---

PC Time stamp 14 OCT 2020 06:26

PC Open Date & Time 13 OCT 2020 12:00

PC Close Date & Time 14 OCT 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(15)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 15

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 14 OCT 2020 13:41

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(16)

Generated On: 26 Nov 2020 11:00:19

**TIMEPOINT**

DAY 16

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

PC Time stamp 16 OCT 2020 02:17

PC Open Date & Time 15 OCT 2020 12:00

PC Close Date & Time 16 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(17)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 17

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 16 OCT 2020 12:08

PC Open Date & Time 16 OCT 2020 12:00

PC Close Date & Time 17 OCT 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(18)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 18

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

---

PC Time stamp 17 OCT 2020 15:00

PC Open Date & Time 17 OCT 2020 12:00

PC Close Date & Time 18 OCT 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(19)

Generated On: 26 Nov 2020 11:00:19

**TIMEPOINT**

DAY 19

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 18 OCT 2020 12:10

PC Open Date & Time 18 OCT 2020 12:00

PC Close Date & Time 19 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(20)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 20

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

---

PC Time stamp 19 OCT 2020 16:38

PC Open Date & Time 19 OCT 2020 12:00

PC Close Date & Time 20 OCT 2020 11:59

---



US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(21)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 21

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

---

PC Time stamp 20 OCT 2020 12:39

PC Open Date & Time 20 OCT 2020 12:00

PC Close Date & Time 21 OCT 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(22)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 22

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

---

PC Time stamp 21 OCT 2020 12:04

PC Open Date & Time 21 OCT 2020 12:00

PC Close Date & Time 22 OCT 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(23)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 23

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

---

PC Time stamp 22 OCT 2020 12:08

PC Open Date & Time 22 OCT 2020 12:00

PC Close Date & Time 23 OCT 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(24)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 24

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

---

PC Time stamp 23 OCT 2020 12:00

PC Open Date & Time 23 OCT 2020 12:00

PC Close Date & Time 24 OCT 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(25)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 25

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 24 OCT 2020 17:55

PC Open Date & Time 24 OCT 2020 12:00

PC Close Date & Time 25 OCT 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(26)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 26

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

---

PC Time stamp 25 OCT 2020 13:14

PC Open Date & Time 25 OCT 2020 12:00

PC Close Date & Time 26 OCT 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(27)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 27

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 26 OCT 2020 12:00

PC Open Date & Time 26 OCT 2020 12:00

PC Close Date & Time 27 OCT 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(28)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 28

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

---

PC Time stamp 27 OCT 2020 12:15

PC Open Date & Time 27 OCT 2020 12:00

PC Close Date & Time 28 OCT 2020 11:59

---



US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(29)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 29

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

---

PC Time stamp 28 OCT 2020 13:15

PC Open Date & Time 28 OCT 2020 12:00

PC Close Date & Time 29 OCT 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(30)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 30

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

---

PC Time stamp 29 OCT 2020 13:11

PC Open Date & Time 29 OCT 2020 12:00

PC Close Date & Time 30 OCT 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(31)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 31

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

---

PC Time stamp 30 OCT 2020 12:00

PC Open Date & Time 30 OCT 2020 12:00

PC Close Date & Time 31 OCT 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(32)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 32

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

---

PC Time stamp 31 OCT 2020 16:56

PC Open Date & Time 31 OCT 2020 12:00

PC Close Date & Time 01 NOV 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(33)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 33

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

---

PC Time stamp 01 NOV 2020 14:03

PC Open Date & Time 01 NOV 2020 12:00

PC Close Date & Time 02 NOV 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(34)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 34

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

---

PC Time stamp 02 NOV 2020 17:31

PC Open Date & Time 02 NOV 2020 12:00

PC Close Date & Time 03 NOV 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(35)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 35

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

---

PC Time stamp 03 NOV 2020 18:01

PC Open Date & Time 03 NOV 2020 12:00

PC Close Date & Time 04 NOV 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(36)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 36

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

---

PC Time stamp 05 NOV 2020 06:41

PC Open Date & Time 04 NOV 2020 12:00

PC Close Date & Time 05 NOV 2020 11:59

---



US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(37)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 37

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 05 NOV 2020 12:13

PC Open Date & Time 05 NOV 2020 12:00

PC Close Date & Time 06 NOV 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(38)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 38

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

---

PC Time stamp 07 NOV 2020 04:41

PC Open Date & Time 06 NOV 2020 12:00

PC Close Date & Time 07 NOV 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(39)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 39

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

---

PC Time stamp 07 NOV 2020 12:30

PC Open Date & Time 07 NOV 2020 12:00

PC Close Date & Time 08 NOV 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(40)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 40

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

---

PC Time stamp 08 NOV 2020 12:00

PC Open Date & Time 08 NOV 2020 12:00

PC Close Date & Time 09 NOV 2020 11:59

---

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(41)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 41

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

---

PC Time stamp 09 NOV 2020 21:21

PC Open Date & Time 09 NOV 2020 12:00

PC Close Date & Time 10 NOV 2020 11:59

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US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(42)

Generated On: 26 Nov 2020 11:00:19

TIMEPOINT

DAY 42

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

PC Time stamp 11 NOV 2020 04:15

PC Open Date & Time 10 NOV 2020 12:00

PC Close Date & Time 11 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(43)

Generated On: 26 Nov 2020 11:00:19

TIMEPOINT

DAY 43

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

PC Time stamp 11 NOV 2020 17:04

PC Open Date & Time 11 NOV 2020 12:00

PC Close Date & Time 12 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(44)

Generated On: 26 Nov 2020 11:00:19

**TIMEPOINT**

DAY 44

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

PC Time stamp 12 NOV 2020 14:39

PC Open Date & Time 12 NOV 2020 12:00

PC Close Date & Time 13 NOV 2020 11:59



US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(45)

Generated On: 26 Nov 2020 11:00:19

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**TIMEPOINT**

DAY 45

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

---

PC Time stamp 13 NOV 2020 18:17

PC Open Date & Time 13 NOV 2020 12:00

PC Close Date & Time 14 NOV 2020 11:59

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US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(46)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 46

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 15 NOV 2020 04:11

PC Open Date & Time 14 NOV 2020 12:00

PC Close Date & Time 15 NOV 2020 11:59

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US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(47)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 47

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

---

PC Time stamp 15 NOV 2020 15:24

PC Open Date & Time 15 NOV 2020 12:00

PC Close Date & Time 16 NOV 2020 11:59

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US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(48)

Generated On: 26 Nov 2020 11:00:19

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**TIMEPOINT**

DAY 48

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

---

PC Time stamp 16 NOV 2020 13:51

PC Open Date & Time 16 NOV 2020 12:00

PC Close Date & Time 17 NOV 2020 11:59

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US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(49)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 49

Select one response below to indicate the intensity of your **JOINT**

**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

---

PC Time stamp 18 NOV 2020 00:03

PC Open Date & Time 17 NOV 2020 12:00

PC Close Date & Time 18 NOV 2020 11:59

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US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(50)

Generated On: 26 Nov 2020 11:00:19

**TIMEPOINT**

DAY 50

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

PC Time stamp 18 NOV 2020 12:33

PC Open Date & Time 18 NOV 2020 12:00

PC Close Date & Time 19 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(51)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 51

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

---

PC Time stamp 20 NOV 2020 05:59

PC Open Date & Time 19 NOV 2020 12:00

PC Close Date & Time 20 NOV 2020 11:59

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US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(52)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 52

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

---

PC Time stamp 21 NOV 2020 04:06

PC Open Date & Time 20 NOV 2020 12:00

PC Close Date & Time 21 NOV 2020 11:59

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US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(53)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 53

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 22 NOV 2020 00:46

PC Open Date & Time 21 NOV 2020 12:00

PC Close Date & Time 22 NOV 2020 11:59

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US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(54)

Generated On: 26 Nov 2020 11:00:19

**TIMEPOINT**

DAY 54

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

PC Time stamp 22 NOV 2020 17:30

PC Open Date & Time 22 NOV 2020 12:00

PC Close Date & Time 23 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(55)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 55

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

---

PC Time stamp 23 NOV 2020 12:02

PC Open Date & Time 23 NOV 2020 12:00

PC Close Date & Time 24 NOV 2020 11:59

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US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(56)

Generated On: 26 Nov 2020 11:00:19

---

**TIMEPOINT**

DAY 56

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

---

PC Time stamp 24 NOV 2020 13:09

PC Open Date & Time 24 NOV 2020 12:00

PC Close Date & Time 25 NOV 2020 11:59

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US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(57)

Generated On: 26 Nov 2020 11:00:19

**TIMEPOINT**

DAY 57

Select one response below to indicate the intensity of your **JOINT**

None ☐

**ACHES IN SEVERAL JOINTS**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

25 NOV 2020 12:00

PC Close Date & Time

26 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(58)

Generated On: 26 Nov 2020 11:00:19

**TIMEPOINT**

DAY 58

Select one response below to indicate the intensity of your **JOINT**

None ☐

**ACHES IN SEVERAL JOINTS**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

26 NOV 2020 12:00

PC Close Date & Time

27 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 26 Nov 2020 11:00:19

<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	07 OCT 2020 16:49
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	08 OCT 2020 12:00
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59



US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 10
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	09 OCT 2020 12:15
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 11
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	10 OCT 2020 12:04
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(12)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 12
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 OCT 2020 17:27
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(13)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 13
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input type="radio"/> Yes <input checked="" type="radio"/>
PC Time stamp	12 OCT 2020 16:02
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(14)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 14
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	14 OCT 2020 06:26
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(15)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 15
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	14 OCT 2020 13:41
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(16)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 16
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	16 OCT 2020 02:17
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(17)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 17
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	16 OCT 2020 12:08
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59



US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(18)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 18
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	17 OCT 2020 15:00
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(19)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 19
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	18 OCT 2020 12:10
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(20)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 20
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	19 OCT 2020 16:38
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(21)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 21
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 OCT 2020 12:39
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(22)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 22
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	21 OCT 2020 12:04
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(23)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 23
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	22 OCT 2020 12:08
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(24)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 24
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	23 OCT 2020 12:00
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(25)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 25
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	24 OCT 2020 18:10
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59



US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(26)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 26
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	25 OCT 2020 13:15
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(27)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 27
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	26 OCT 2020 12:00
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(28)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 28
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	27 OCT 2020 12:15
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(29)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 29
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	28 OCT 2020 13:15
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(30)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 30
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	29 OCT 2020 13:11
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(31)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 31
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	30 OCT 2020 12:00
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(32)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 32
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	31 OCT 2020 16:57
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(33)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 33
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	01 NOV 2020 14:20
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59



US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(34)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 34
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 NOV 2020 17:32
PC Open Date & Time	02 NOV 2020 12:00
PC Close Date & Time	03 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(35)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 35
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="radio"/> Yes <input checked="" type="radio"/>
PC Time stamp	03 NOV 2020 18:02
PC Open Date & Time	03 NOV 2020 12:00
PC Close Date & Time	04 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(36)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 36
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	05 NOV 2020 06:41
PC Open Date & Time	04 NOV 2020 12:00
PC Close Date & Time	05 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(37)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 37
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	05 NOV 2020 12:13
PC Open Date & Time	05 NOV 2020 12:00
PC Close Date & Time	06 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(38)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 38
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	07 NOV 2020 04:42
PC Open Date & Time	06 NOV 2020 12:00
PC Close Date & Time	07 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(39)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 39
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	07 NOV 2020 12:30
PC Open Date & Time	07 NOV 2020 12:00
PC Close Date & Time	08 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(40)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 40
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	08 NOV 2020 12:01
PC Open Date & Time	08 NOV 2020 12:00
PC Close Date & Time	09 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(41)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 41
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	09 NOV 2020 21:21
PC Open Date & Time	09 NOV 2020 12:00
PC Close Date & Time	10 NOV 2020 11:59



US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(42)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 42
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 NOV 2020 04:16
PC Open Date & Time	10 NOV 2020 12:00
PC Close Date & Time	11 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(43)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 43
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 NOV 2020 17:05
PC Open Date & Time	11 NOV 2020 12:00
PC Close Date & Time	12 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(44)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 44
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	12 NOV 2020 14:39
PC Open Date & Time	12 NOV 2020 12:00
PC Close Date & Time	13 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(45)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 45
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	13 NOV 2020 18:17
PC Open Date & Time	13 NOV 2020 12:00
PC Close Date & Time	14 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(46)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 46
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	15 NOV 2020 04:11
PC Open Date & Time	14 NOV 2020 12:00
PC Close Date & Time	15 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(47)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 47
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	15 NOV 2020 15:24
PC Open Date & Time	15 NOV 2020 12:00
PC Close Date & Time	16 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(48)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 48
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	16 NOV 2020 13:51
PC Open Date & Time	16 NOV 2020 12:00
PC Close Date & Time	17 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(49)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 49
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 NOV 2020 00:04
PC Open Date & Time	17 NOV 2020 12:00
PC Close Date & Time	18 NOV 2020 11:59



US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(50)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 50
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	18 NOV 2020 12:33
PC Open Date & Time	18 NOV 2020 12:00
PC Close Date & Time	19 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(51)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 51
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	20 NOV 2020 05:59
PC Open Date & Time	19 NOV 2020 12:00
PC Close Date & Time	20 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(52)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 52
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	21 NOV 2020 04:06
PC Open Date & Time	20 NOV 2020 12:00
PC Close Date & Time	21 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(53)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 53
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	22 NOV 2020 00:46
PC Open Date & Time	21 NOV 2020 12:00
PC Close Date & Time	22 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(54)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 54
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	22 NOV 2020 17:30
PC Open Date & Time	22 NOV 2020 12:00
PC Close Date & Time	23 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(55)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 55
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	23 NOV 2020 12:02
PC Open Date & Time	23 NOV 2020 12:00
PC Close Date & Time	24 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(56)

Generated On: 26 Nov 2020 11:00:19

<b>TIMEPOINT</b>	DAY 56
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 NOV 2020 13:10
PC Open Date & Time	24 NOV 2020 12:00
PC Close Date & Time	25 NOV 2020 11:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(57)

Generated On: 26 Nov 2020 11:00:19

**TIMEPOINT**

DAY 57

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

25 NOV 2020 12:00

PC Close Date & Time

26 NOV 2020 11:59



US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(58)

Generated On: 26 Nov 2020 11:00:19

**TIMEPOINT**

DAY 58

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

26 NOV 2020 12:00

PC Close Date & Time

27 NOV 2020 11:59

US3342200

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:19

Was Contact Attempted?

Yes ☒

No ☐

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

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342200

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342200

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:19

Was Contact Attempted?

Yes ☒

No ☐

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

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342200

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342200

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:19

Was Contact Attempted?

Yes ☒

No ☐

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

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342200

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342200

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:00:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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



US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	26 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	15:30 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 15:30
Temperature ( <i>xxx.x</i> )	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	71 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342200

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 OCT 2020

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

US3342200

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	26 OCT 2020
Collection time ( <i>00:00-23:59</i> )	17:06 (24 HR)
Collection date and time (derived)	26 OCT 2020 17:06

US3342200

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

**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

04 NOV 2020 09:43:22

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3342200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 04:16:48

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3342200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 00:04:41

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>



**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

01 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2020 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

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[Patient Cloud Open Date & Time](#)

08 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

12 NOV 2020 23:59

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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	22 NOV 2020 00:48:10
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

29 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59



US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

**TIMEPOINT**

DAY 103

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

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

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

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

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

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

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

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

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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="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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

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[Patient Cloud Close Date & Time](#)

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24 DEC 2020 23:59

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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

31 DEC 2020 23:59



US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

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[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

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[Patient Cloud Open Date & Time](#)

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17 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 JAN 2021 23:59

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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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



US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

07 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 FEB 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 FEB 2021 23:59



US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 MAR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 MAR 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 MAR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 MAR 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

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[Patient Cloud Open Date & Time](#)

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21 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAR 2021 23:59

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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

11 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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



US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

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[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

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[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

**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 ☐

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

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[Patient Cloud Open Date & Time](#)

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16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAY 2021 23:59

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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

30 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59



US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

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[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

**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 ☐

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

**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 ☐

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

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[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

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[Patient Cloud Open Date & Time](#)

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26 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 SEP 2021 23:59

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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 OCT 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 NOV 2021 23:59
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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

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[Patient Cloud Open Date & Time](#)

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28 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	05 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	09 DEC 2021 23:59
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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

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

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

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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



US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

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[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

**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 ☐

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

**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 ☐

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 JAN 2022 23:59



US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

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[Patient Cloud Open Date & Time](#)

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30 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 FEB 2022 23:59

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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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 ☐

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

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[Patient Cloud Close Date & Time](#)

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10 FEB 2022 23:59

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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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 <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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

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[Patient Cloud Close Date & Time](#)

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24 FEB 2022 23:59

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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

**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 ☐

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

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[Patient Cloud Open Date & Time](#)

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06 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAR 2022 23:59

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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

**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 ☐

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

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[Patient Cloud Close Date & Time](#)

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17 MAR 2022 23:59

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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

**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 ☐

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	20 MAR 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 MAR 2022 23:59
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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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 ☐

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

**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 ☐

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

**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 ☐

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

**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 ☐

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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



US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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



US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2022 23:59

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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

29 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

**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 ☐

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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



US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

**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 ☐

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

**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 ☐

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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



US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

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[Patient Cloud Close Date & Time](#)

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04 AUG 2022 23:59

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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59



US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

**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 ☐

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 OCT 2022 23:59

US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3342200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

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

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[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

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US3342200

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:19

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*

US3342200

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3342200**

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

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:00:19**

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*

**US3342200**

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

**Form: Continuing**

**Generated On: 26 Nov 2020 11:00:19**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3342200

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:00:19

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"/>

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3342200

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:00:19

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:19

AEID	
Adverse event	ATOPIC DERMATITIS EXACERBATION
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	04 SEP 2020
Start time (00:00-23:59)	22:00 (24 HR)
AE start date and time (derived)	04 SEP 2020 22:00
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
v6.020 DTW (1102)	
465 of 2531	

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:19

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

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:00:19

AEID	
Adverse event	MYALGIA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	5 OCT 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)	16 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:00:19

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

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:00:19

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	4 OCT 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)	16 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

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US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:00:19

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

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

AEID	USA-US203-2020-MRNA-1273-P30 1000006
Adverse event	DUCTAL CARCINOMA IN SITU RIGHT BREAST
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)	20 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

v6.020 DTW (1102)

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US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input 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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

---

PATIENT HAD AN ABNORMAL  
MAMMOGRAM AUG2020 RIGHT  
BREAST AND HAD A RIGHT  
BREAST BIOSPY. RESULTS  
FROM AUG2020 BIOSPY WERE  
BENIGN. PATIENT HAD  
ANNUAL EXAM OCT2020 AND  
WAS TOLD BY PROVIDER TO  
HAVE ANOTHER  
MAMMOGRAM AND U/S OF  
RIGHT BREAST DUE TO  
ANOTHER RIGHT BREAST  
LUMP. PATIENT HAD  
MAMMOGRAM AND U/S  
OCT2020 AND THEN HAD A  
BIOPSY OF RIGHT BREAST  
18NOV2020. PATIENT WAS  
DIAGNOSED WITH DUCTAL  
CARCINOMA IN SITU OF THE  
RIGHT BREAST FOLLOWING  
BIOPSY ON 20NOV2020.  
PATIENT WILL BE SEEING  
BREAST CANCER SPECIALIST  
AND HAS NOT STARTED  
MEDICATION OR RADIATION  
AT THIS TIME.

---

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)	

---

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:00:19

---

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

Yes ☒

No ☐

---

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

---

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:19

Name of Medication	VITAMIN D
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	VITAMIN D DEFICIENCY
Dose per administration	5000
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input checked="" 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"/>

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:19

	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 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)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" type="radio"/>
	804	<input type="radio"/>

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:19

Name of Medication	SINGULAIR
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SEASONAL ALLERGIES
Dose per administration	10
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input checked="" type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:19

	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 2010
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"/>

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:19

Name of Medication	FLU VACCINE
Prophylaxis	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

Indication	INFLUENZA PREVENTION
------------	----------------------

Dose per administration	1
-------------------------	---

Dose unit	mg <input type="radio"/>
	ug <input type="radio"/>
	mL <input type="radio"/>
	g <input type="radio"/>
	IU <input type="radio"/>
	tablet <input type="radio"/>
	capsule <input type="radio"/>
	puff <input type="radio"/>
	Other <input checked="" type="radio"/>

If dose unit is Other, specify	INJECTION
--------------------------------	-----------

Frequency	once daily <input type="radio"/>
	twice daily <input type="radio"/>
	three times daily <input type="radio"/>
	four times daily <input type="radio"/>
	every other day <input type="radio"/>
	every week <input type="radio"/>
	every month <input type="radio"/>
	as needed <input type="radio"/>
	once <input checked="" type="radio"/>
	unknown <input type="radio"/>
	other <input type="radio"/>

If frequency is Other, specify	
--------------------------------	--

Route of administration	Oral <input type="radio"/>
	Topical <input type="radio"/>
	Subcutaneous <input type="radio"/>
	Transdermal <input type="radio"/>
	Intraocular <input type="radio"/>
	Intramuscular <input checked="" type="radio"/>



US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:19

	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 ( <i>dd MMM yyyy</i> )		05 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date ( <i>dd MMM yyyy</i> )		05 AUG 2020
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" 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"/>

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:19

Name of Medication	TRIAMCINOLONE 1%
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ATOPIC DERMATITIS
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	APPLICATION
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 type="radio"/> Topical <input checked="" type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:19

	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 ( <i>dd MMM yyyy</i> )	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date ( <i>dd MMM yyyy</i> ) <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"/>

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:00:19

Name of Medication	ACETAMINOPHEN EXTRA STRENGTH
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	HEADACHE (SOLICITED REACTION - VACCINE #2)
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 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 checked="" 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"/>

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:00:19

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 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)		03 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:19

Name of Medication	TRIAMCINOLONE 0.1%
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	ATOPIC DERMATITIS EXACERBATION AE
Dose per administration	1
Dose unit	mg <input 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 checked="" type="checkbox"/>
If dose unit is Other, specify	APPLICATION
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input checked="" type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/> Topical <input checked="" type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:19

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		04 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)		16 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3342200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:00:19

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.



US3342200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 11:00:19

Procedure/Surgery date ( <i>dd MMM</i> <i>yyyy</i> )	Procedure/Surgery	Indication	If indication is Other, specify
18 NOV 2020	RIGHT BREAST LUMP BIOPSY	Diagnostic	

US3342200

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:00:19

---

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

---

US3342200

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:00:19

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 ☐

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:19

SAEID	USA-US203-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:00:19

SAEID	USA-US203-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	24/NOV/2020 20:40
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

US3342200 (Prod: Tekton Research- Austin)

**US3342200**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 11:00:19**

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3342200'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	04 Sep 2020 21:19:32

US3342200

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:00:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Sep 2020 21:45:17



US3342200

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	04 Sep 2020 21:19:33

US3342200

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Stefanie Mott (b) (4)	04 Sep 2020 21:45:17

**US3342200**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:00:19**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	04 Sep 2020 21:45:17

US3342200

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:19

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1975'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	04 Sep 2020 21:19:34

US3342200

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:19

[Age](#)

Audit	User	Time (GMT)
User entered '44'	Stefanie Mott (b) (4)	04 Sep 2020 21:45:43

**US3342200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 11:00:19**

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	04 Sep 2020 21:45:43

**US3342200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 11:00:19**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '44'	System	04 Sep 2020 21:46:03

US3342200

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:19

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	Stefanie Mott (b) (4)	04 Sep 2020 21:45:43



US3342200

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:19

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Stefanie Mott (b) (4)	04 Sep 2020 21:45:43

US3342200

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:19

White

Audit	User	Time (GMT)
User entered '1'	Stefanie Mott (b) (4)	04 Sep 2020 21:45:43

**US3342200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 11:00:19**

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 21:45:43

**US3342200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 11:00:19**

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 21:45:43

US3342200

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:19

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 21:45:43

US3342200

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:19

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 21:45:43

US3342200

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:19

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 21:45:43

US3342200

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:19

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:45:43



US3342200

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:19

Unknown

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 21:45:43

US3342200

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:19

Not reported

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 21:45:43

US3342200

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:00:19

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '4 Sep 2020'	Stefanie Mott (b) (4)	04 Sep 2020 21:46:03

**US3342200**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	04 Sep 2020 21:46:03

**US3342200**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered '2020'	System	04 Sep 2020 21:46:03

US3342200

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:00:19

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	Stefanie Mott (b) (4)	04 Sep 2020 21:46:03

US3342200

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Sep 2020 21:46:03

US3342200

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:00:19

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:46:03



US3342200

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:00:19

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:46:03

US3342200

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:00:19

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 21:46:03

US3342200

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:00:19

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	04 Sep 2020 21:19:33

**US3342200**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 11:00:19**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Sep 2020 21:46:11

US3342200

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:00:19

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Sep 2020 21:46:11

US3342200

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:00:19

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Sep 2020 21:46:17

US3342200

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:00:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 21:58:40
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 21:58:40
Data point term sent to Coder	System	04 Sep 2020 21:57:41
User entered 'HYSTERECTOMY'	Stefanie Mott (b) (4) (b) (4) (b) (4)	04 Sep 2020 21:57:17

US3342200

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered '12 Nov 2018'	Stefanie Mott (b) (4)	04 Sep 2020 21:57:17



US3342200

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:00:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 21:57:17

US3342200

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:00:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 21:58:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 21:58:13
User entered 'No (N)' reason for change: Data Entry Error	Stefanie Mott (b) (4) [REDACTED]	04 Sep 2020 21:58:13
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 21:57:17
User entered empty.	Stefanie Mott (b) (4) [REDACTED]	04 Sep 2020 21:57:17

**US3342200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered '12 Nov 2018' reason for change: Data Entry Error	Stefanie Mott (b) (4)	04 Sep 2020 21:58:13
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:57:17

**US3342200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 11:00:19**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 21:57:17

**US3342200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered 'Nov 2018'	System	04 Sep 2020 21:57:17

**US3342200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered '2018'	System	04 Sep 2020 21:57:17

**US3342200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered 'Nov 2018'	System	04 Sep 2020 21:58:13
User entered empty.	System	04 Sep 2020 21:57:17

**US3342200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered '2018'	System	04 Sep 2020 21:58:13
User entered empty.	System	04 Sep 2020 21:57:17



US3342200

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:00:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Investigations, imaging and histopathology procedures NEC, HLT: Investigations NEC, PT: Precancerous cells present, LLT: Precancerous cells present - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 07:10:57
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 07:10:57
Data point term sent to Coder	System	04 Sep 2020 21:59:43
User entered 'Precancerous cervical cells'	Stefanie Mott (b) (4) (b) (4) (b) (4)	04 Sep 2020 21:59:06

**US3342200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	Stefanie Mott (b) (4)	04 Sep 2020 21:59:06

**US3342200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:00:19**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 21:59:06

US3342200

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:00:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 21:59:06

**US3342200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered '12 Nov 2018'	Stefanie Mott (b) (4)	04 Sep 2020 21:59:06

**US3342200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:00:19**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 21:59:06

**US3342200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	04 Sep 2020 21:59:06

**US3342200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered '2018'	System	04 Sep 2020 21:59:06



**US3342200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered 'Nov 2018'	System	04 Sep 2020 21:59:06

**US3342200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered '2018'	System	04 Sep 2020 21:59:06

US3342200

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:00:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 22:00:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 22:00:42
Data point term sent to Coder	System	04 Sep 2020 21:59:43
User entered 'Kidney stones'	Stefanie Mott (b) (4)	04 Sep 2020 21:59:37

**US3342200**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered 'UN UNK 2019'	Stefanie Mott (b) (4)	04 Sep 2020 21:59:37

**US3342200**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:00:19**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 21:59:37

**US3342200**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:00:19**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 21:59:37

**US3342200**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered 'UN UNK 2019'	Stefanie Mott (b) (4)	04 Sep 2020 21:59:37

**US3342200**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:00:19**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 21:59:37



**US3342200**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	04 Sep 2020 21:59:37

**US3342200**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered '2019'	System	04 Sep 2020 21:59:37

**US3342200**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	04 Sep 2020 21:59:37

**US3342200**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered '2019'	System	04 Sep 2020 21:59:37

US3342200

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:00:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 22:01:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 22:01:43
Data point term sent to Coder	System	04 Sep 2020 22:00:44
User entered 'Seasonal allergies'	Stefanie Mott (b) (4)	04 Sep 2020 21:59:57

US3342200

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 1993'	Stefanie Mott (b) (4)	04 Sep 2020 21:59:57

**US3342200**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:00:19**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 21:59:57

**US3342200**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:00:19**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Sep 2020 21:59:57



US3342200

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:59:57

**US3342200**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:00:19**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 21:59:57

**US3342200**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered 'Jan 1993'	System	04 Sep 2020 21:59:57

**US3342200**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered '1993'	System	04 Sep 2020 21:59:57

**US3342200**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 21:59:57

**US3342200**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 21:59:57

US3342200

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:00:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis atopic, LLT: Atopic dermatitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 22:01:42
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 22:01:42
Data point term sent to Coder	System	04 Sep 2020 22:00:46
User entered 'Atopic dermatitis'	Stefanie Mott (b) (4) (b) (4) (b) (4)	04 Sep 2020 22:00:23

**US3342200**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered 'UN UNK 1990'	Stefanie Mott (b) (4)	04 Sep 2020 22:00:23



**US3342200**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 11:00:19**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 22:00:23

US3342200

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:00:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Sep 2020 22:00:23

US3342200

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 22:00:23

**US3342200**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 11:00:19**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 22:00:23

**US3342200**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	04 Sep 2020 22:00:23

**US3342200**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered '1990'	System	04 Sep 2020 22:00:23

**US3342200**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 22:00:23

**US3342200**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 22:00:23



US3342200

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:00:19

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Rubber sensitivity, LLT: Latex allergy - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 23:20:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 23:20:45
Data point term sent to Coder	System	04 Sep 2020 22:10:02
Coding entries removed.	Stefanie Mott (b) (4)	04 Sep 2020 22:09:48
User entered 'LATEX ALLERGY - hives' reason for change: Data Entry Error	Stefanie Mott (b) (4)	04 Sep 2020 22:09:48
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Rubber sensitivity, LLT: Latex allergy - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 22:01:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 22:01:43
Data point term sent to Coder	System	04 Sep 2020 22:00:46
User entered 'Latex allergy'	Stefanie Mott (b) (4)	04 Sep 2020 22:00:44

**US3342200**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered 'UN UNK 1993'	Stefanie Mott (b) (4)	04 Sep 2020 22:00:44

**US3342200**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 11:00:19**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 22:00:44

**US3342200**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 11:00:19**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Sep 2020 22:00:44

US3342200

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 22:00:44

**US3342200**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 11:00:19**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 22:00:44

**US3342200**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered 'Jan 1993'	System	04 Sep 2020 22:00:44

**US3342200**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered '1993'	System	04 Sep 2020 22:00:44



**US3342200**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 22:00:44

**US3342200**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 22:00:44

US3342200

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:00:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 22:02:44
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 22:02:44
Data point term sent to Coder	System	04 Sep 2020 22:01:48
User entered 'Vitamin D deficiency'	Stefanie Mott (b) (4) (b) (4) (b) (4)	04 Sep 2020 22:01:13

US3342200

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Stefanie Mott (b) (4)	04 Sep 2020 22:01:13

US3342200

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:00:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 22:01:13

**US3342200**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 11:00:19**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Sep 2020 22:01:13

US3342200

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 22:01:13

**US3342200**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 11:00:19**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 22:01:13



**US3342200**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	04 Sep 2020 22:01:13

**US3342200**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered '2015'	System	04 Sep 2020 22:01:13

**US3342200**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 22:01:13

**US3342200**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 22:01:13

US3342200

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:00:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in joint involving shoulder region - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 17:29:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 17:29:44
Data point term sent to Coder	System	30 Sep 2020 17:18:46
User entered 'Joint Pain Bilateral Shoulders '	(b) (4), (b) (6) (b) (4)	30 Sep 2020 17:17:58

US3342200

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered 'UN May 2020'	(b) (4), (b) (6)	30 Sep 2020 17:17:58

**US3342200**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:00:19**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 17:17:58

**US3342200**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:00:19**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 17:17:58



US3342200

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 17:17:58

US3342200

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:00:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 17:17:58

**US3342200**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered 'May 2020'	System	30 Sep 2020 17:17:58

**US3342200**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered '2020'	System	30 Sep 2020 17:17:58

**US3342200**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 17:17:58

**US3342200**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 17:17:58

US3342200

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:00:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Pain in extremity, LLT: Pain of lower extremities - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 17:55:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 17:55:54
Data point term sent to Coder	System	30 Sep 2020 17:18:47
User entered 'Bilateral Pain Bilateral lower Extremities'	(b) (4), (b) (6) (b) (4)	30 Sep 2020 17:18:43

US3342200

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 2020'	(b) (4), (b) (6)	30 Sep 2020 17:18:43



US3342200

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:00:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 17:18:43

US3342200

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:00:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 17:18:43

**US3342200**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 17:18:43

**US3342200**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 11:00:19**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 17:18:43

**US3342200**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered 'Jan 2020'	System	30 Sep 2020 17:18:43

**US3342200**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered '2020'	System	30 Sep 2020 17:18:43

**US3342200**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 17:18:43

**US3342200**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 17:18:43



US3342200

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:00:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms benign (incl nipple), HLT: Breast and nipple neoplasms benign, PT: Benign breast neoplasm, LLT: Breast lump (benign) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 23:05:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 23:05:04
Data point term sent to Coder	System	23 Nov 2020 23:03:38
User entered 'right breast lump benign'	Stefanie Mott (b) (4) (b) (4) (b) (4)	23 Nov 2020 23:03:22

US3342200

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered 'un Aug 2020'	Stefanie Mott (b) (4)	23 Nov 2020 23:03:22

**US3342200**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 11:00:19**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	23 Nov 2020 23:03:22

US3342200

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:00:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	23 Nov 2020 23:03:22

US3342200

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered 'un Aug 2020'	Stefanie Mott (b) (4)	23 Nov 2020 23:03:22

US3342200

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:00:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	23 Nov 2020 23:03:22

**US3342200**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	23 Nov 2020 23:03:22

**US3342200**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered '2020'	System	23 Nov 2020 23:03:22



**US3342200**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	23 Nov 2020 23:03:22

**US3342200**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered '2020'	System	23 Nov 2020 23:03:22

US3342200

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:00:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Reproductive organ and breast investigations (excl hormone analyses), HLT: Reproductive organ and breast histopathology procedures, PT: Biopsy breast, LLT: Breast lump biopsy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 08:10:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 08:10:16
Data point term sent to Coder	System	23 Nov 2020 23:04:39
User entered 'right breast lump biopsy'	Stefanie Mott (b) (4) (b) (4) (b) (4)	23 Nov 2020 23:03:48

US3342200

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered 'un Aug 2020'	Stefanie Mott (b) (4)	23 Nov 2020 23:03:48

US3342200

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:00:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	23 Nov 2020 23:03:48

US3342200

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:00:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	23 Nov 2020 23:03:48

US3342200

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered 'un Aug 2020'	Stefanie Mott (b) (4)	23 Nov 2020 23:03:48

**US3342200**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 11:00:19**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	23 Nov 2020 23:03:48



**US3342200**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	23 Nov 2020 23:03:48

**US3342200**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered '2020'	System	23 Nov 2020 23:03:48

**US3342200**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	23 Nov 2020 23:03:48

**US3342200**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered '2020'	System	23 Nov 2020 23:03:48

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Sep 2020 21:47:54

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '4 Sep 2020'	Stefanie Mott (b) (4)	04 Sep 2020 21:47:54

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered '15:59'	Stefanie Mott (b) (4)	04 Sep 2020 21:47:54

**US3342200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered '4 Sep 2020 15:59'	System	04 Sep 2020 21:47:54



US3342200

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:19

Height (xxx.x)

Audit	User	Time (GMT)
User entered '163.5' cm	Stefanie Mott (b) (4)	04 Sep 2020 21:47:54
DataPoint set to visible.	System	04 Sep 2020 21:46:11

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:19

Weight (xxx.x)

Audit	User	Time (GMT)
User entered '065.4' kg	Stefanie Mott (b) (4)	04 Sep 2020 21:47:54
DataPoint set to visible.	System	04 Sep 2020 21:46:11

**US3342200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered '24.46483'	System	04 Sep 2020 21:47:54
DataPoint set to visible.	System	04 Sep 2020 21:46:11

**US3342200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:00:19**

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	04 Sep 2020 21:47:54
DataPoint set to visible.	System	04 Sep 2020 21:46:11

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stefanie Mott (b) (4)	04 Sep 2020 21:47:54

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:47:54

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:47:54

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stefanie Mott (b) (4)	04 Sep 2020 21:47:54



**US3342200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:00:19**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	04 Sep 2020 21:47:54

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stefanie Mott (b) (4)	04 Sep 2020 21:47:54

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	04 Sep 2020 21:47:54

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stefanie Mott (b) (4)	04 Sep 2020 21:47:54

**US3342200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:00:19**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Sep 2020 21:47:54

US3342200

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stefanie Mott (b) (4)	04 Sep 2020 21:47:54

**US3342200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:00:19**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Sep 2020 21:47:54

US3342200

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:19

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Sep 2020 21:48:07



US3342200

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '4 Sep 2020'	Stefanie Mott (b) (4)	04 Sep 2020 21:48:07

US3342200

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:00:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '4 Sep 2020'	Stefanie Mott (b) (4)	04 Sep 2020 21:50:18

US3342200

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:00:19

Is the participant of childbearing potential?

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 21:50:18

US3342200

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered 'Surgically sterile (SURGICALLY STERILE)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	04 Sep 2020 21:50:18

US3342200

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:00:19

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:50:18

US3342200

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User closed query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	04 Sep 2020 22:02:01
User entered '12 Nov 2018' reason for change: Data Entry Error	Stefanie Mott (b) (4) [REDACTED]	04 Sep 2020 22:02:01
User opened query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	04 Sep 2020 21:50:18
User entered empty.	Stefanie Mott (b) (4) [REDACTED]	04 Sep 2020 21:50:18

US3342200

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:00:19

Date of surgery unknown

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 21:50:18

US3342200

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	04 Sep 2020 21:50:18



US3342200

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:00:19

Date of last menstruation unknown

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 21:50:18

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:19

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	04 Sep 2020 21:51:01



US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:19

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:19

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:19

**No Risk Identified**

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	04 Sep 2020 21:51:01



US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered 'I'	Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:19

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:19

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:51:01

US3342200

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:00:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Sep 2020 21:51:17

US3342200

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:00:19

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '4 Sep 2020'	Stefanie Mott (b) (4)	04 Sep 2020 21:51:17



US3342200

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Stefanie Mott (b) (4)	04 Sep 2020 21:51:17

**US3342200**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:00:19**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	04 Sep 2020 21:51:17

US3342200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	04 Sep 2020 21:24:20

US3342200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:00:19

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '111836'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	04 Sep 2020 21:24:20

US3342200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	04 Sep 2020 21:24:20

US3342200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 22:10:53

US3342200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	04 Sep 2020 22:10:53

US3342200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 22:10:53



US3342200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:00:19

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 22:10:53

US3342200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:00:19

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 22:10:53

**US3342200**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:30:57
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:30:56

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:00:19

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:00:19

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:00:19

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:00:19

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:19

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19



US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:19

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '4 Sep 2020'	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered '15:59'	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

**US3342200**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered '4 Sep 2020 15:59'	System	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.4' F	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '73'	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19



**US3342200**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 11:00:19**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered '12'	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '115'	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '79'	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:00:19

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19



US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:00:19

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:19

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 22:29:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 22:29:21
User entered 'Yes (Y)' reason for change: Data Entry Error	Stefanie Mott (b) (4) [REDACTED]	04 Sep 2020 22:29:21
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 21:54:19
User entered empty.	Stefanie Mott (b) (4) [REDACTED]	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '4 Sep 2020' reason for change: Data Entry Error	Stefanie Mott (b) (4) [REDACTED]	04 Sep 2020 22:29:21
User entered empty.	Stefanie Mott (b) (4) [REDACTED]	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered '17:21' reason for change: Data Entry Error	Stefanie Mott (b) (4)	04 Sep 2020 22:29:21
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

**US3342200**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered '4 Sep 2020 17:21'	System	04 Sep 2020 22:29:21
User entered empty.	System	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.7' F reason for change: Data Entry Error	Stefanie Mott (b) (4)	04 Sep 2020 22:29:21
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	Stefanie Mott (b) (4)	04 Sep 2020 22:29:21
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19



US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '81' reason for change: Data Entry Error	Stefanie Mott (b) (4)	04 Sep 2020 22:29:21
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

**US3342200**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 11:00:19**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	04 Sep 2020 22:29:21
User entered empty.	System	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered '12' reason for change: Data Entry Error	Stefanie Mott (b) (4)	04 Sep 2020 22:29:21
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

**US3342200**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 11:00:19**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	04 Sep 2020 22:29:21
User entered empty.	System	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '109' reason for change: Data Entry Error	Stefanie Mott (b) (4)	04 Sep 2020 22:29:21
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19

**US3342200**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 11:00:19**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Sep 2020 22:29:21
User entered empty.	System	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '80' reason for change: Data Entry Error	Stefanie Mott (b) (4)	04 Sep 2020 22:29:21
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:19



**US3342200**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 11:00:19**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Sep 2020 22:29:21
User entered empty.	System	04 Sep 2020 21:54:19

US3342200

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:19

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 21:54:25

US3342200

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:54:25

US3342200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Sep 2020 21:55:03

US3342200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:19

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:55:03

US3342200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 21:55:03

US3342200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 21:55:03

US3342200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '4 Sep 2020'	Stefanie Mott (b) (4)	04 Sep 2020 21:55:03



US3342200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered '16:51'	Stefanie Mott (b) (4)	04 Sep 2020 21:55:03

**US3342200**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 11:00:19**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '4 Sep 2020 16:51'	System	04 Sep 2020 21:55:03

US3342200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:19

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Stefanie Mott (b) (4)	04 Sep 2020 21:55:03

US3342200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:19

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	04 Sep 2020 21:55:03

US3342200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 21:55:03

US3342200

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:19

Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Sep 2020 22:14:21

US3342200

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '4 Sep 2020'	Stefanie Mott (b) (4)	04 Sep 2020 22:14:21

US3342200

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 20:57:41
User entered '16:24' reason for change: Data Entry Error	Darrell O'Brien (b) (4) (b) (4)	08 Sep 2020 20:57:41
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 22:14:21
User entered empty.	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	04 Sep 2020 22:14:21



**US3342200**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered '4 Sep 2020 16:24'	System	08 Sep 2020 20:57:41
User entered empty.	System	04 Sep 2020 22:14:21

US3342200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:00:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '4 Sep 2020'	Stefanie Mott (b) (4)	04 Sep 2020 22:14:34

US3342200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:00:19

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stefanie Mott (b) (4)	04 Sep 2020 22:14:34

US3342200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:00:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Sep 2020 22:14:34

US3342200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:00:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
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 20:57:54
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 20:57:54
User entered '16:25' reason for change: Data Entry Error	Darrell O'Brien (b) (4) (b) (4)	08 Sep 2020 20:57:54
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 22:14:34
User entered empty.	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	04 Sep 2020 22:14:34

**US3342200**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered '4 Sep 2020 16:25'	System	08 Sep 2020 20:57:54
User entered empty.	System	04 Sep 2020 22:14:34

US3342200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:00:19

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stefanie Mott (b) (4)	04 Sep 2020 22:14:34

US3342200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:00:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 22:14:34



US3342200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:00:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 22:14:34

**US3342200**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 22:14:34

US3342200

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:00:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Sep 2020 22:14:41

**US3342200**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:00:19**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 22:14:41

**US3342200**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:00:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:21:59', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '80fdabaf-6790-46cf-89a0-ce5f5f5ae3c4'	System	04 Sep 2020 22:22:44
User entered 'Yes (Y)'	System	04 Sep 2020 22:22:44

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:00:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:22:30', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '80fdabaf-6790-46cf-89a0-ce5f5f5ae3c4'	System	04 Sep 2020 22:22:44
User entered '98.7'	System	04 Sep 2020 22:22:44

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:22:35', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '80fdabaf-6790-46cf-89a0-ce5f5f5ae3c4'	System	04 Sep 2020 22:22:44
User entered 'No (N)'	System	04 Sep 2020 22:22:44



**US3342200**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:22:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '80fdabaf-6790-46cf-89a0-ce5f5f5ae3c4'	System	04 Sep 2020 22:22:44
User entered '04 Sep 2020 17:22'	System	04 Sep 2020 22:22:44

**US3342200**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 17:11'	System	04 Sep 2020 21:55:03

**US3342200**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 19:41'	System	04 Sep 2020 21:55:03

**US3342200**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 21:55:03

**US3342200**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:39:50', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '21ca14df-9f6b-41d2-a1da-2de5ed8e92bd' User entered 'Yes (Y)'	System	05 Sep 2020 01:40:13

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 11:00:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:40:02', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '21ca14df-9f6b-41d2-a1da-2de5ed8e92bd'	System	05 Sep 2020 01:40:13
User entered '98.4'	System	05 Sep 2020 01:40:13

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:40:06', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '21ca14df-9f6b-41d2-a1da-2de5ed8e92bd'	System	05 Sep 2020 01:40:13
User entered 'No (N)'	System	05 Sep 2020 01:40:13

**US3342200**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:40:12', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '21ca14df-9f6b-41d2-a1da-2de5ed8e92bd' User entered '04 Sep 2020 20:40'	System	05 Sep 2020 01:40:13
	System	05 Sep 2020 01:40:13



**US3342200**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 20:36'	System	04 Sep 2020 21:55:03

**US3342200**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 2'	System	04 Sep 2020 21:55:03

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:01:11', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '57f59e96-b785-4c4a-9907-7e77368c2822'	System	05 Sep 2020 17:02:18
User entered 'Yes (Y)'	System	05 Sep 2020 17:02:18

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:02:02', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '57f59e96-b785-4c4a-9907-7e77368c2822'	System	05 Sep 2020 17:02:18
User entered '97.8'	System	05 Sep 2020 17:02:18

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:02:06', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '57f59e96-b785-4c4a-9907-7e77368c2822'	System	05 Sep 2020 17:02:18
User entered 'No (N)'	System	05 Sep 2020 17:02:18

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:02:09', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '57f59e96-b785-4c4a-9907-7e77368c2822' User entered '05 Sep 2020 12:02'	System	05 Sep 2020 17:02:18
	System	05 Sep 2020 17:02:18

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 21:55:03



**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 3'	System	04 Sep 2020 21:55:03

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:34:46', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd7cfad2a-24c5-4217-943c-deaa6e2ea7d6'	System	06 Sep 2020 23:35:32
User entered 'Yes (Y)'	System	06 Sep 2020 23:35:32

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:35:11', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd7cfad2a-24c5-4217-943c-deaa6e2ea7d6'	System	06 Sep 2020 23:35:32
User entered '97.6'	System	06 Sep 2020 23:35:32

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:35:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd7cfad2a-24c5-4217-943c-deaa6e2ea7d6'	System	06 Sep 2020 23:35:32
User entered 'No (N)'	System	06 Sep 2020 23:35:32

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:35:27', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd7cfad2a-24c5-4217-943c-deaa6e2ea7d6'	System	06 Sep 2020 23:35:32
User entered '06 Sep 2020 18:35'	System	06 Sep 2020 23:35:32

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 21:55:03



**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 4'	System	04 Sep 2020 21:55:03

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:21:19', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8471c8a3-726e-4842-a1ba-2d75431376c1'	System	07 Sep 2020 23:23:11
User entered 'Yes (Y)'	System	07 Sep 2020 23:23:11

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:22:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8471c8a3-726e-4842-a1ba-2d75431376c1' User entered '98.7'	System	07 Sep 2020 23:23:11
	System	07 Sep 2020 23:23:11

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:23:02', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8471c8a3-726e-4842-a1ba-2d75431376c1'	System	07 Sep 2020 23:23:11
User entered 'No (N)'	System	07 Sep 2020 23:23:11

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:23:09', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8471c8a3-726e-4842-a1ba-2d75431376c1'	System	07 Sep 2020 23:23:11
User entered '07 Sep 2020 18:23'	System	07 Sep 2020 23:23:11

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 5'	System	04 Sep 2020 21:55:03



**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:17:17', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'da4a020d-55ef-489f-a8f2-79d25022e900'	System	09 Sep 2020 08:17:42
User entered 'Yes (Y)'	System	09 Sep 2020 08:17:42

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:17:31', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'da4a020d-55ef-489f-a8f2-79d25022e900'	System	09 Sep 2020 08:17:42
User entered '98.7'	System	09 Sep 2020 08:17:42

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:17:37', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'da4a020d-55ef-489f-a8f2-79d25022e900'	System	09 Sep 2020 08:17:42
User entered 'No (N)'	System	09 Sep 2020 08:17:42

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:17:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'da4a020d-55ef-489f-a8f2-79d25022e900'	System	09 Sep 2020 08:17:42
User entered '09 Sep 2020 03:17'	System	09 Sep 2020 08:17:42

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 6'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:00:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:29:14', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '78130293-1561-4205-8668-4e676ea32c56'	System	09 Sep 2020 19:29:30
User entered 'Yes (Y)'	System	09 Sep 2020 19:29:30



**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:29:19', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '78130293-1561-4205-8668-4e676ea32c56'	System	09 Sep 2020 19:29:30
User entered '98.3'	System	09 Sep 2020 19:29:30

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:29:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '78130293-1561-4205-8668-4e676ea32c56'	System	09 Sep 2020 19:29:30
User entered 'No (N)'	System	09 Sep 2020 19:29:30

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:29:27', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '78130293-1561-4205-8668-4e676ea32c56'	System	09 Sep 2020 19:29:30
User entered '09 Sep 2020 14:29'	System	09 Sep 2020 19:29:30

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 7'	System	04 Sep 2020 21:55:03

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:02:48', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fb93657f-e5ab-48d6-9917-41847a303122'	System	10 Sep 2020 17:20:34
User entered 'Yes (Y)'	System	10 Sep 2020 17:20:34

US3342200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 11:00:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:20:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fb93657f-e5ab-48d6-9917-41847a303122'	System	10 Sep 2020 17:20:34
User entered '97.6'	System	10 Sep 2020 17:20:34



US3342200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:20:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fb93657f-e5ab-48d6-9917-41847a303122'	System	10 Sep 2020 17:20:34
User entered 'No (N)'	System	10 Sep 2020 17:20:34

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:20:26', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fb93657f-e5ab-48d6-9917-41847a303122'	System	10 Sep 2020 17:20:34
User entered '10 Sep 2020 12:20'	System	10 Sep 2020 17:20:34

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

**US3342200**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:23:04', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '844cef55-7307-4b34-ab47-6113932c85e3'	System	04 Sep 2020 22:24:03
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 22:24:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:23:08', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '844cef55-7307-4b34-ab47-6113932c85e3' User entered 'No (N)'	System	04 Sep 2020 22:24:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:23:12', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '844cef55-7307-4b34-ab47-6113932c85e3'	System	04 Sep 2020 22:24:03
User entered 'No (N)'	System	04 Sep 2020 22:24:03



US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:23:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '844cef55-7307-4b34-ab47-6113932c85e3' User entered 'None (1)'	System	04 Sep 2020 22:24:03
	System	04 Sep 2020 22:24:03

**US3342200**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:23:59', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '844cef55-7307-4b34-ab47-6113932c85e3' User entered '04 Sep 2020 17:23'	System	04 Sep 2020 22:24:03
	System	04 Sep 2020 22:24:03

**US3342200**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 17:11'	System	04 Sep 2020 21:55:03

**US3342200**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 19:41'	System	04 Sep 2020 21:55:03

**US3342200**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:40:26', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e57835c9-83d0-47a5-9486-50860c25bbcd'	System	05 Sep 2020 01:40:48
User entered 'None (1)'	System	05 Sep 2020 01:40:48

**US3342200**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:40:29', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e57835c9-83d0-47a5-9486-50860c25bbcd'	System	05 Sep 2020 01:40:48
User entered 'No (N)'	System	05 Sep 2020 01:40:48

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:40:34', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e57835c9-83d0-47a5-9486-50860c25bbcd'	System	05 Sep 2020 01:40:48
User entered 'No (N)'	System	05 Sep 2020 01:40:48



US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:40:43', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e57835c9-83d0-47a5-9486-50860c25bbcd'	System	05 Sep 2020 01:40:48
User entered 'None (1)'	System	05 Sep 2020 01:40:48

**US3342200**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:40:46', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e57835c9-83d0-47a5-9486-50860c25bbcd' User entered '04 Sep 2020 20:40'	System	05 Sep 2020 01:40:48
	System	05 Sep 2020 01:40:48

**US3342200**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 20:36'	System	04 Sep 2020 21:55:03

**US3342200**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

**US3342200**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 2'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:02:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'edd2a3b3-6a13-4d41-bd85-5c0b2052eb23'	System	05 Sep 2020 17:03:01
User entered 'None (1)'	System	05 Sep 2020 17:03:01

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:02:46', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'edd2a3b3-6a13-4d41-bd85-5c0b2052eb23'	System	05 Sep 2020 17:03:01
User entered 'No (N)'	System	05 Sep 2020 17:03:01

**US3342200**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:02:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'edd2a3b3-6a13-4d41-bd85-5c0b2052eb23'	System	05 Sep 2020 17:03:01
User entered 'No (N)'	System	05 Sep 2020 17:03:01



**US3342200**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 11:00:19**

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:02:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'edd2a3b3-6a13-4d41-bd85-5c0b2052eb23'	System	05 Sep 2020 17:03:01
User entered 'None (1)'	System	05 Sep 2020 17:03:01

**US3342200**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:02:59', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'edd2a3b3-6a13-4d41-bd85-5c0b2052eb23' User entered '05 Sep 2020 12:02'	System	05 Sep 2020 17:03:01

**US3342200**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

**US3342200**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

**US3342200**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 3'	System	04 Sep 2020 21:55:03

**US3342200**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 11:00:19**

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:35:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '34ac097e-052c-4f3a-afad-6bed5229d2c6'	System	06 Sep 2020 23:36:26
User entered 'None (1)'	System	06 Sep 2020 23:36:26

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 11:00:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:35:42', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '34ac097e-052c-4f3a-afad-6bed5229d2c6'	System	06 Sep 2020 23:36:26
User entered 'No (N)'	System	06 Sep 2020 23:36:26

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:35:57', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '34ac097e-052c-4f3a-afad-6bed5229d2c6'	System	06 Sep 2020 23:36:26
User entered 'No (N)'	System	06 Sep 2020 23:36:26



US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:36:21', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '34ac097e-052c-4f3a-afad-6bed5229d2c6'	System	06 Sep 2020 23:36:26
User entered 'None (1)'	System	06 Sep 2020 23:36:26

**US3342200**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:36:24', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '34ac097e-052c-4f3a-afad-6bed5229d2c6'	System	06 Sep 2020 23:36:26
User entered '06 Sep 2020 18:36'	System	06 Sep 2020 23:36:26

**US3342200**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

**US3342200**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

**US3342200**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 4'	System	04 Sep 2020 21:55:03

**US3342200**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 11:00:19**

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:23:26', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0f169d51-4674-4faa-92d1-a58b38b47e30'	System	07 Sep 2020 23:23:47
User entered 'None (1)'	System	07 Sep 2020 23:23:47

**US3342200**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:23:31', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0f169d51-4674-4faa-92d1-a58b38b47e30'	System	07 Sep 2020 23:23:47
User entered 'No (N)'	System	07 Sep 2020 23:23:47

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:23:37', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0f169d51-4674-4faa-92d1-a58b38b47e30'	System	07 Sep 2020 23:23:47
User entered 'No (N)'	System	07 Sep 2020 23:23:47



US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:23:43', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0f169d51-4674-4faa-92d1-a58b38b47e30'	System	07 Sep 2020 23:23:47
User entered 'None (1)'	System	07 Sep 2020 23:23:47

**US3342200**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:23:46', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0f169d51-4674-4faa-92d1-a58b38b47e30'	System	07 Sep 2020 23:23:47
User entered '07 Sep 2020 18:23'	System	07 Sep 2020 23:23:47

**US3342200**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

**US3342200**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

**US3342200**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 5'	System	04 Sep 2020 21:55:03

**US3342200**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 11:00:19**

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:17:45', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '71b5e4ba-8749-4b68-b2df-2609433d1a61'	System	09 Sep 2020 08:18:00
User entered 'None (1)'	System	09 Sep 2020 08:18:00

**US3342200**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:17:48', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '71b5e4ba-8749-4b68-b2df-2609433d1a61'	System	09 Sep 2020 08:18:00
User entered 'No (N)'	System	09 Sep 2020 08:18:00

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:17:51', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '71b5e4ba-8749-4b68-b2df-2609433d1a61'	System	09 Sep 2020 08:18:00
User entered 'No (N)'	System	09 Sep 2020 08:18:00



US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:17:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '71b5e4ba-8749-4b68-b2df-2609433d1a61'	System	09 Sep 2020 08:18:00
User entered 'None (1)'	System	09 Sep 2020 08:18:00

**US3342200**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:17:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '71b5e4ba-8749-4b68-b2df-2609433d1a61' User entered '09 Sep 2020 03:17'	System	09 Sep 2020 08:18:00
	System	09 Sep 2020 08:18:00

**US3342200**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

**US3342200**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

**US3342200**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 6'	System	04 Sep 2020 21:55:03

**US3342200**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 11:00:19**

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:29:32', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a24a57ad-dcb2-4bb0-a3a8-db7c2946dcd5' User entered 'None (1)'	System	09 Sep 2020 19:29:47
	System	09 Sep 2020 19:29:47

**US3342200**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:29:35', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a24a57ad-dcb2-4bb0-a3a8-db7c2946dcd5'	System	09 Sep 2020 19:29:47
User entered 'No (N)'	System	09 Sep 2020 19:29:47

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:29:38', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a24a57ad-dcb2-4bb0-a3a8-db7c2946dcd5'	System	09 Sep 2020 19:29:47
User entered 'No (N)'	System	09 Sep 2020 19:29:47



**US3342200**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 11:00:19**

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:29:42', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a24a57ad-dcb2-4bb0-a3a8-db7c2946dcd5' User entered 'None (1)'	System	09 Sep 2020 19:29:47
	System	09 Sep 2020 19:29:47

**US3342200**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:29:44', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a24a57ad-dcb2-4bb0-a3a8-db7c2946dcd5' User entered '09 Sep 2020 14:29'	System	09 Sep 2020 19:29:47
	System	09 Sep 2020 19:29:47

**US3342200**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

**US3342200**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

**US3342200**

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

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 7'	System	04 Sep 2020 21:55:03

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:20:32', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '96c4b03c-2b80-4dad-8231-74e19634a9ef'	System	10 Sep 2020 17:20:48
User entered 'None (1)'	System	10 Sep 2020 17:20:48

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:00:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:20:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '96c4b03c-2b80-4dad-8231-74e19634a9ef'	System	10 Sep 2020 17:20:48
User entered 'No (N)'	System	10 Sep 2020 17:20:48

US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:20:39', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '96c4b03c-2b80-4dad-8231-74e19634a9ef'	System	10 Sep 2020 17:20:48
User entered 'No (N)'	System	10 Sep 2020 17:20:48



US3342200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:20:42', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '96c4b03c-2b80-4dad-8231-74e19634a9ef' User entered 'None (1)'	System	10 Sep 2020 17:20:48
	System	10 Sep 2020 17:20:48

**US3342200**

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

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:20:44', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '96c4b03c-2b80-4dad-8231-74e19634a9ef' User entered '10 Sep 2020 12:20'	System	10 Sep 2020 17:20:48
	System	10 Sep 2020 17:20:48

**US3342200**

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

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

**US3342200**

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

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

**US3342200**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 21:55:03

**US3342200**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:24:09', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '95b07862-cd3e-4682-aaec-8b707ab91e54'	System	04 Sep 2020 22:24:44
User entered 'None (0)'	System	04 Sep 2020 22:24:44

**US3342200**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:24:12', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '95b07862-cd3e-4682-aaec-8b707ab91e54' User entered 'None (0)'	System	04 Sep 2020 22:24:44
	System	04 Sep 2020 22:24:44

**US3342200**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:24:18', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '95b07862-cd3e-4682-aaec-8b707ab91e54' User entered 'None (0)'	System	04 Sep 2020 22:24:44
	System	04 Sep 2020 22:24:44



US3342200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:00:19

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:24:23', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '95b07862-cd3e-4682-aaec-8b707ab91e54'	System	04 Sep 2020 22:24:44
User entered 'None (0)'	System	04 Sep 2020 22:24:44

**US3342200**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:24:26', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '95b07862-cd3e-4682-aaec-8b707ab91e54'	System	04 Sep 2020 22:24:44
User entered 'None (0)'	System	04 Sep 2020 22:24:44

**US3342200**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:24:30', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '95b07862-cd3e-4682-aaec-8b707ab91e54'	System	04 Sep 2020 22:24:44
User entered 'None (0)'	System	04 Sep 2020 22:24:44

US3342200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:24:37', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '95b07862-cd3e-4682-aaec-8b707ab91e54'	System	04 Sep 2020 22:24:44
User entered 'No (N)'	System	04 Sep 2020 22:24:44

**US3342200**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T17:24:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '95b07862-cd3e-4682-aaec-8b707ab91e54'	System	04 Sep 2020 22:24:44
User entered '04 Sep 2020 17:24'	System	04 Sep 2020 22:24:44

**US3342200**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 17:11'	System	04 Sep 2020 21:55:03

**US3342200**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 19:41'	System	04 Sep 2020 21:55:03

**US3342200**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 21:55:03



**US3342200**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:40:59', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7a915e8c-5ffe-45f7-b01a-ab9dcbbd6e85'	System	05 Sep 2020 01:41:27
User entered 'None (0)'	System	05 Sep 2020 01:41:27

**US3342200**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:41:02', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7a915e8c-5ffe-45f7-b01a-ab9dcbbd6e85'	System	05 Sep 2020 01:41:27
User entered 'None (0)'	System	05 Sep 2020 01:41:27

**US3342200**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:41:05', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7a915e8c-5ffe-45f7-b01a-ab9dcbbd6e85'	System	05 Sep 2020 01:41:27
User entered 'None (0)'	System	05 Sep 2020 01:41:27

**US3342200**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:41:09', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7a915e8c-5ffe-45f7-b01a-ab9dcbbd6e85'	System	05 Sep 2020 01:41:27
User entered 'None (0)'	System	05 Sep 2020 01:41:27

**US3342200**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:41:11', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7a915e8c-5ffe-45f7-b01a-ab9dcbbd6e85'	System	05 Sep 2020 01:41:27
User entered 'None (0)'	System	05 Sep 2020 01:41:27

**US3342200**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:41:14', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7a915e8c-5ffe-45f7-b01a-ab9dcbbd6e85'	System	05 Sep 2020 01:41:27
User entered 'None (0)'	System	05 Sep 2020 01:41:27

US3342200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:41:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7a915e8c-5ffe-45f7-b01a-ab9dcbbd6e85'	System	05 Sep 2020 01:41:27
User entered 'No (N)'	System	05 Sep 2020 01:41:27

**US3342200**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-04T20:41:25', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7a915e8c-5ffe-45f7-b01a-ab9dcbbd6e85'	System	05 Sep 2020 01:41:27
User entered '04 Sep 2020 20:41'	System	05 Sep 2020 01:41:27



**US3342200**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 20:36'	System	04 Sep 2020 21:55:03

**US3342200**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 2'	System	04 Sep 2020 21:55:03

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:03:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd3fff3df-a0e5-4844-96ec-98147dc31128'	System	05 Sep 2020 17:03:36
User entered 'None (0)'	System	05 Sep 2020 17:03:36

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:03:06', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd3fff3df-a0e5-4844-96ec-98147dc31128'	System	05 Sep 2020 17:03:36
User entered 'None (0)'	System	05 Sep 2020 17:03:36

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:03:09', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd3fff3df-a0e5-4844-96ec-98147dc31128'	System	05 Sep 2020 17:03:36
User entered 'None (0)'	System	05 Sep 2020 17:03:36

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:03:14', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd3fff3df-a0e5-4844-96ec-98147dc31128'	System	05 Sep 2020 17:03:36
User entered 'None (0)'	System	05 Sep 2020 17:03:36

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:03:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd3fff3df-a0e5-4844-96ec-98147dc31128'	System	05 Sep 2020 17:03:36
User entered 'None (0)'	System	05 Sep 2020 17:03:36



**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:03:19', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd3fff3df-a0e5-4844-96ec-98147dc31128'	System	05 Sep 2020 17:03:36
User entered 'None (0)'	System	05 Sep 2020 17:03:36

US3342200

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:03:23', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd3fff3df-a0e5-4844-96ec-98147dc31128'	System	05 Sep 2020 17:03:36
User entered 'No (N)'	System	05 Sep 2020 17:03:36

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-05T12:03:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd3fff3df-a0e5-4844-96ec-98147dc31128'	System	05 Sep 2020 17:03:36
User entered '05 Sep 2020 12:03'	System	05 Sep 2020 17:03:36

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 3'	System	04 Sep 2020 21:55:03

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:36:32', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1b78fdd8-a347-42b4-946d-5862f33981ed' User entered 'None (0)'	System	06 Sep 2020 23:37:11
	System	06 Sep 2020 23:37:11

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:36:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1b78fdd8-a347-42b4-946d-5862f33981ed' User entered 'None (0)'	System	06 Sep 2020 23:37:11
	System	06 Sep 2020 23:37:11



**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:36:44', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1b78fdd8-a347-42b4-946d-5862f33981ed' User entered 'None (0)'	System	06 Sep 2020 23:37:11
	System	06 Sep 2020 23:37:11

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:36:51', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1b78fdd8-a347-42b4-946d-5862f33981ed' User entered 'None (0)'	System	06 Sep 2020 23:37:11
	System	06 Sep 2020 23:37:11

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:36:56', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1b78fdd8-a347-42b4-946d-5862f33981ed' User entered 'None (0)'	System	06 Sep 2020 23:37:11
	System	06 Sep 2020 23:37:11

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:36:59', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1b78fdd8-a347-42b4-946d-5862f33981ed' User entered 'None (0)'	System	06 Sep 2020 23:37:11
	System	06 Sep 2020 23:37:11

US3342200

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:37:04', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1b78fdd8-a347-42b4-946d-5862f33981ed'	System	06 Sep 2020 23:37:11
User entered 'No (N)'	System	06 Sep 2020 23:37:11

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-06T18:37:09', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1b78fdd8-a347-42b4-946d-5862f33981ed' User entered '06 Sep 2020 18:37'	System	06 Sep 2020 23:37:11
	System	06 Sep 2020 23:37:11

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 21:55:03



**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 4'	System	04 Sep 2020 21:55:03

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:23:53', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9ba9383a-0590-4b1c-86cb-7e82d29d5666'	System	07 Sep 2020 23:24:32
User entered 'None (0)'	System	07 Sep 2020 23:24:32

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:23:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9ba9383a-0590-4b1c-86cb-7e82d29d5666'	System	07 Sep 2020 23:24:32
User entered 'None (0)'	System	07 Sep 2020 23:24:32

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:24:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9ba9383a-0590-4b1c-86cb-7e82d29d5666'	System	07 Sep 2020 23:24:32
User entered 'None (0)'	System	07 Sep 2020 23:24:32

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:24:10', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9ba9383a-0590-4b1c-86cb-7e82d29d5666'	System	07 Sep 2020 23:24:32
User entered 'None (0)'	System	07 Sep 2020 23:24:32

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:24:13', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9ba9383a-0590-4b1c-86cb-7e82d29d5666'	System	07 Sep 2020 23:24:32
User entered 'None (0)'	System	07 Sep 2020 23:24:32

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:24:17', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9ba9383a-0590-4b1c-86cb-7e82d29d5666'	System	07 Sep 2020 23:24:32
User entered 'None (0)'	System	07 Sep 2020 23:24:32

US3342200

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:24:24', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9ba9383a-0590-4b1c-86cb-7e82d29d5666'	System	07 Sep 2020 23:24:32
User entered 'No (N)'	System	07 Sep 2020 23:24:32



**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-07T18:24:27', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9ba9383a-0590-4b1c-86cb-7e82d29d5666'	System	07 Sep 2020 23:24:32
User entered '07 Sep 2020 18:24'	System	07 Sep 2020 23:24:32

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 5'	System	04 Sep 2020 21:55:03

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:18:04', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '90155f4b-9974-40b4-abef-3dc586523a30' User entered 'None (0)'	System	09 Sep 2020 08:18:28
	System	09 Sep 2020 08:18:28

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:18:05', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '90155f4b-9974-40b4-abef-3dc586523a30' User entered 'None (0)'	System	09 Sep 2020 08:18:28
	System	09 Sep 2020 08:18:28

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:18:08', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '90155f4b-9974-40b4-abef-3dc586523a30' User entered 'None (0)'	System	09 Sep 2020 08:18:28
	System	09 Sep 2020 08:18:28

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:18:12', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '90155f4b-9974-40b4-abef-3dc586523a30' User entered 'None (0)'	System	09 Sep 2020 08:18:28
	System	09 Sep 2020 08:18:28



**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:18:14', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '90155f4b-9974-40b4-abef-3dc586523a30'	System	09 Sep 2020 08:18:28
User entered 'None (0)'	System	09 Sep 2020 08:18:28

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:18:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '90155f4b-9974-40b4-abef-3dc586523a30' User entered 'None (0)'	System	09 Sep 2020 08:18:28
	System	09 Sep 2020 08:18:28

US3342200

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:18:21', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '90155f4b-9974-40b4-abef-3dc586523a30'	System	09 Sep 2020 08:18:28
User entered 'No (N)'	System	09 Sep 2020 08:18:28

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T03:18:26', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '90155f4b-9974-40b4-abef-3dc586523a30'	System	09 Sep 2020 08:18:28
User entered '09 Sep 2020 03:18'	System	09 Sep 2020 08:18:28

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 6'	System	04 Sep 2020 21:55:03

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:29:50', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '39a54276-2e6b-465d-aabd-8810be393315'	System	09 Sep 2020 19:30:20
User entered 'None (0)'	System	09 Sep 2020 19:30:20



**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:29:53', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '39a54276-2e6b-465d-aabd-8810be393315'	System	09 Sep 2020 19:30:20
User entered 'None (0)'	System	09 Sep 2020 19:30:20

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:29:55', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '39a54276-2e6b-465d-aabd-8810be393315' User entered 'None (0)'	System	09 Sep 2020 19:30:20

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:29:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '39a54276-2e6b-465d-aabd-8810be393315'	System	09 Sep 2020 19:30:20
User entered 'None (0)'	System	09 Sep 2020 19:30:20

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:30:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '39a54276-2e6b-465d-aabd-8810be393315'	System	09 Sep 2020 19:30:20
User entered 'None (0)'	System	09 Sep 2020 19:30:20

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:30:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '39a54276-2e6b-465d-aabd-8810be393315'	System	09 Sep 2020 19:30:20
User entered 'None (0)'	System	09 Sep 2020 19:30:20

US3342200

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:30:07', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '39a54276-2e6b-465d-aabd-8810be393315'	System	09 Sep 2020 19:30:20
User entered 'No (N)'	System	09 Sep 2020 19:30:20

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-09T14:30:18', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '39a54276-2e6b-465d-aabd-8810be393315' User entered '09 Sep 2020 14:30'	System	09 Sep 2020 19:30:20
	System	09 Sep 2020 19:30:20

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 21:55:03



**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 7'	System	04 Sep 2020 21:55:03

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:20:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ce9444c4-67c9-4b96-93be-eba69a4eb82f' User entered 'None (0)'	System	10 Sep 2020 17:21:11
	System	10 Sep 2020 17:21:11

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:20:51', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ce9444c4-67c9-4b96-93be-eba69a4eb82f' User entered 'None (0)'	System	10 Sep 2020 17:21:11
	System	10 Sep 2020 17:21:11

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:20:53', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ce9444c4-67c9-4b96-93be-eba69a4eb82f' User entered 'None (0)'	System	10 Sep 2020 17:21:11
	System	10 Sep 2020 17:21:11

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:20:56', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ce9444c4-67c9-4b96-93be-eba69a4eb82f' User entered 'None (0)'	System	10 Sep 2020 17:21:11
	System	10 Sep 2020 17:21:11

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:20:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ce9444c4-67c9-4b96-93be-eba69a4eb82f' User entered 'None (0)'	System	10 Sep 2020 17:21:11
	System	10 Sep 2020 17:21:11

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:21:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ce9444c4-67c9-4b96-93be-eba69a4eb82f' User entered 'None (0)'	System	10 Sep 2020 17:21:11
	System	10 Sep 2020 17:21:11



US3342200

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:21:05', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ce9444c4-67c9-4b96-93be-eba69a4eb82f'	System	10 Sep 2020 17:21:11
User entered 'No (N)'	System	10 Sep 2020 17:21:11

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-10T12:21:09', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ce9444c4-67c9-4b96-93be-eba69a4eb82f' User entered '10 Sep 2020 12:21'	System	10 Sep 2020 17:21:11
	System	10 Sep 2020 17:21:11

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 21:55:03

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 21:55:03

US3342200

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	14 Sep 2020 19:49:49

US3342200

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Ethan Shotton (b) (4) (b) (4)	14 Sep 2020 19:49:49

**US3342200**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:00:19**

[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)	14 Sep 2020 19:49:49

**US3342200**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:00:19**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	14 Sep 2020 19:49:49



US3342200

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	14 Sep 2020 19:49:55

**US3342200**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:00:19**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Sep 2020 19:49:55

US3342200

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	21 Sep 2020 19:27:42

**US3342200**

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

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Ethan Shotton (b) (4) (b) (4)	21 Sep 2020 19:27:42

**US3342200**

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

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:00:19**

[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)	21 Sep 2020 19:27:42

**US3342200**

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

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:00:19**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	21 Sep 2020 19:27:42

US3342200

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	21 Sep 2020 19:27:47

**US3342200**

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

**Form: Continuing**

**Generated On: 26 Nov 2020 11:00:19**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Sep 2020 19:27:47



US3342200

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 21:51:48

US3342200

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 21:51:48

**US3342200**

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

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:00:19**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Sep 2020 21:51:48

**US3342200**

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

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:00:19**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 21:51:48

US3342200

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Morgan Schulle (b) (4)	30 Sep 2020 16:21:02
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 21:51:51

**US3342200**

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

**Form: Continuing**

**Generated On: 26 Nov 2020 11:00:19**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Sep 2020 16:21:02
User entered empty.	System	28 Sep 2020 21:51:51

US3342200

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:00:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	30 Sep 2020 16:21:23

US3342200

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	30 Sep 2020 16:21:23



US3342200

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:00:19

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)	30 Sep 2020 16:21:23

**US3342200**

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

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:00:19**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	30 Sep 2020 16:21:23

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:19

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:19

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered '10:20'	(b) (4), (b) (6)	30 Sep 2020 16:30:46

**US3342200**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered '30 Sep 2020 10:20'	System	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.7' F	(b) (4), (b) (6)	30 Sep 2020 16:30:46



US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 16:30:46

**US3342200**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 11:00:19**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '77'	(b) (4), (b) (6)	30 Sep 2020 16:30:46

**US3342200**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 11:00:19**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered '14'	(b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '116'	(b) (4), (b) (6)	30 Sep 2020 16:30:46

**US3342200**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 11:00:19**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 16:30:46



US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '79'	(b) (4), (b) (6)	30 Sep 2020 16:30:46

**US3342200**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 11:00:19**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:19

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 16:36:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 16:36:46
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 16:36:46
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 16:30:46
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 16:36:46
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered '11:32' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 16:36:46
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 16:30:46

**US3342200**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:32'	System	30 Sep 2020 16:36:46
User entered empty.	System	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '99.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 16:36:46
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 16:30:46



US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 16:36:46
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '71' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 16:36:46
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 16:30:46

**US3342200**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 11:00:19**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Sep 2020 16:36:46
User entered empty.	System	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered '12' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 16:36:46
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Sep 2020 16:36:46
User entered empty.	System	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered '107' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 16:36:46
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 16:30:46

**US3342200**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 11:00:19**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 16:36:46
User entered empty.	System	30 Sep 2020 16:30:46



US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered '68' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 16:36:46
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 16:36:46
User entered empty.	System	30 Sep 2020 16:30:46

US3342200

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:19

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	30 Sep 2020 16:22:02

US3342200

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	30 Sep 2020 16:22:02

US3342200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 16:25:19

US3342200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:19

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 16:25:19

US3342200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 16:25:19

**US3342200**

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

**Form: Exposure**

**Generated On: 26 Nov 2020 11:00:19**

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	30 Sep 2020 16:25:19



US3342200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 16:25:19

US3342200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:19

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:59'	(b) (4), (b) (6)	30 Sep 2020 16:25:19

**US3342200**

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

**Form: Exposure**

**Generated On: 26 Nov 2020 11:00:19**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 10:59'	System	30 Sep 2020 16:25:19

US3342200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:19

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	30 Sep 2020 16:25:19

US3342200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:19

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	30 Sep 2020 16:25:19

US3342200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	30 Sep 2020 16:25:19

US3342200

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	06 Oct 2020 13:26:23

US3342200

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	06 Oct 2020 13:26:23



US3342200

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '10:48'	Morgan Schulle (b) (4) (b) (4)	06 Oct 2020 13:26:23

**US3342200**

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

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered '30 Sep 2020 10:48'	System	06 Oct 2020 13:26:23

US3342200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:00:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	06 Oct 2020 13:26:39

US3342200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:00:19

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Morgan Schulle (b) (4)	06 Oct 2020 13:26:39

US3342200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:00:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	06 Oct 2020 13:26:39

**US3342200**

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

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 11:00:19**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
User entered '10:50'	Morgan Schulle (b) (4) (b) (4)	06 Oct 2020 13:26:39

**US3342200**

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

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered '30 Sep 2020 10:50'	System	06 Oct 2020 13:26:39

US3342200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:00:19

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Morgan Schulle (b) (4) (b) (4)	06 Oct 2020 13:26:39



US3342200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:00:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	06 Oct 2020 13:26:39

US3342200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:00:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	06 Oct 2020 13:26:39

**US3342200**

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

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 11:00:19**

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

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 13:26:39

US3342200

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	30 Sep 2020 16:22:35

**US3342200**

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

**Form: Continuing**

**Generated On: 26 Nov 2020 11:00:19**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Sep 2020 16:22:35

**US3342200**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:00:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:37:10', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '69b20c6c-7e46-4b4f-82e4-e0c556c34484'	System	30 Sep 2020 16:37:36
User entered 'Yes (Y)'	System	30 Sep 2020 16:37:36

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:00:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:37:17', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '69b20c6c-7e46-4b4f-82e4-e0c556c34484' User entered '99.1'	System	30 Sep 2020 16:37:36
	System	30 Sep 2020 16:37:36



US3342200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:37:24', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '69b20c6c-7e46-4b4f-82e4-e0c556c34484'	System	30 Sep 2020 16:37:36
User entered 'No (N)'	System	30 Sep 2020 16:37:36

**US3342200**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:37:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '69b20c6c-7e46-4b4f-82e4-e0c556c34484' User entered '30 Sep 2020 11:37'	System	30 Sep 2020 16:37:36
	System	30 Sep 2020 16:37:36

**US3342200**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:19'	System	30 Sep 2020 16:25:19

**US3342200**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 13:49'	System	30 Sep 2020 16:25:19

**US3342200**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 11:00:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:41:11', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '75eb22fd-cb96-43ec-8c5e-a65bc7db10b5'	System	01 Oct 2020 11:41:33
User entered 'Yes (Y)'	System	01 Oct 2020 11:41:33

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 11:00:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:41:19', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '75eb22fd-cb96-43ec-8c5e-a65bc7db10b5' User entered '98.6'	System	01 Oct 2020 11:41:33
	System	01 Oct 2020 11:41:33

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:41:23', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '75eb22fd-cb96-43ec-8c5e-a65bc7db10b5'	System	01 Oct 2020 11:41:33
User entered 'No (N)'	System	01 Oct 2020 11:41:33



**US3342200**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:41:28', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '75eb22fd-cb96-43ec-8c5e-a65bc7db10b5' User entered '01 Oct 2020 06:41'	System	01 Oct 2020 11:41:33
	System	01 Oct 2020 11:41:33

**US3342200**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 14:44'	System	30 Sep 2020 16:25:19

**US3342200**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 2'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 11:00:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:00:24', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '47b29698-b5fc-4dea-b609-547b865c0914'	System	01 Oct 2020 17:01:01
User entered 'Yes (Y)'	System	01 Oct 2020 17:01:01

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 11:00:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:00:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '47b29698-b5fc-4dea-b609-547b865c0914' User entered '98.7'	System	01 Oct 2020 17:01:01

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:00:45', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '47b29698-b5fc-4dea-b609-547b865c0914'	System	01 Oct 2020 17:01:01
User entered 'No (N)'	System	01 Oct 2020 17:01:01

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:00:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '47b29698-b5fc-4dea-b609-547b865c0914' User entered '01 Oct 2020 12:00'	System	01 Oct 2020 17:01:01
	System	01 Oct 2020 17:01:01



**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 3'	System	30 Sep 2020 16:25:19

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:00:57', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dfefe34b-2e99-47a8-953a-a47392d9c6cc'	System	02 Oct 2020 17:03:22
User entered 'Yes (Y)'	System	02 Oct 2020 17:03:22

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 11:00:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:03:08', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dfefe34b-2e99-47a8-953a-a47392d9c6cc' User entered '98.0'	System	02 Oct 2020 17:03:22

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:03:12', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dfefe34b-2e99-47a8-953a-a47392d9c6cc'	System	02 Oct 2020 17:03:22
User entered 'No (N)'	System	02 Oct 2020 17:03:22

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:03:18', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dfefe34b-2e99-47a8-953a-a47392d9c6cc' User entered '02 Oct 2020 12:03'	System	02 Oct 2020 17:03:22
	System	02 Oct 2020 17:03:22

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 16:25:19



**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

**US3342200**

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

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

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 4'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:00:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T06:58:46', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a0c3f0fa-befc-46ac-863c-aabd3c7caa32'	System	04 Oct 2020 12:02:50
User entered 'Yes (Y)'	System	04 Oct 2020 12:02:50

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:00:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:01:37', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a0c3f0fa-befc-46ac-863c-aabd3c7caa32'	System	04 Oct 2020 12:02:50
User entered '98.7'	System	04 Oct 2020 12:02:50

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:00:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:02:08', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a0c3f0fa-befc-46ac-863c-aabd3c7caa32'	System	04 Oct 2020 12:02:50
User entered 'Yes (Y)'	System	04 Oct 2020 12:02:50

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:00:19

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). 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 'Medication taken has been recorded and EDC updated.' (Site from System).	(b) (4), (b) (6) (b) (4)	09 Nov 2020 16:46:12
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:02:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a0c3f0fa-befc-46ac-863c-aabd3c7caa32' User entered '1'	Olivia Hapanowicz (b) (4) System System System	05 Nov 2020 22:58:01 04 Oct 2020 12:02:50 04 Oct 2020 12:02:50 04 Oct 2020 12:02:50

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 11:00:19

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:02:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a0c3f0fa-befc-46ac-863c-aabd3c7caa32'	System	04 Oct 2020 12:02:50
User entered '0'	System	04 Oct 2020 12:02:50

**US3342200**

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

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:02:48', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a0c3f0fa-befc-46ac-863c-aabd3c7caa32'	System	04 Oct 2020 12:02:50
User entered '04 Oct 2020 07:02'	System	04 Oct 2020 12:02:50



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 5'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 11:00:19**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:33:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fd3eb3d4-b289-473a-a3f3-cb2fd5779705'	System	04 Oct 2020 17:34:18
User entered 'Yes (Y)'	System	04 Oct 2020 17:34:18

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 11:00:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:34:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fd3eb3d4-b289-473a-a3f3-cb2fd5779705'	System	04 Oct 2020 17:34:18
User entered '98.1'	System	04 Oct 2020 17:34:18

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 11:00:19

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:34:06', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fd3eb3d4-b289-473a-a3f3-cb2fd5779705'	System	04 Oct 2020 17:34:18
User entered 'No (N)'	System	04 Oct 2020 17:34:18

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:34:15', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fd3eb3d4-b289-473a-a3f3-cb2fd5779705'	System	04 Oct 2020 17:34:18
User entered '04 Oct 2020 12:34'	System	04 Oct 2020 17:34:18

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 16:25:19



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 6'	System	30 Sep 2020 16:25:19

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:00:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:34:17', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '45924544-388c-46be-b865-5ab22528e85f'	System	06 Oct 2020 07:34:53
User entered 'Yes (Y)'	System	06 Oct 2020 07:34:53

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:00:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:34:31', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '45924544-388c-46be-b865-5ab22528e85f' User entered '97.6'	System	06 Oct 2020 07:34:53

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 11:00:19

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:34:39', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '45924544-388c-46be-b865-5ab22528e85f' User entered 'No (N)'	System	06 Oct 2020 07:34:53

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:34:48', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '45924544-388c-46be-b865-5ab22528e85f' User entered '06 Oct 2020 02:34'	System	06 Oct 2020 07:34:53
	System	06 Oct 2020 07:34:53

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 16:25:19



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 7'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 11:00:19**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:15:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd3c3a384-d8f8-4078-b06b-72927dff565f'	System	07 Oct 2020 09:29:12
User entered 'Yes (Y)'	System	07 Oct 2020 09:29:12

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 11:00:19**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:28:53', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd3c3a384-d8f8-4078-b06b-72927dff565f'	System	07 Oct 2020 09:29:12
User entered '98.4'	System	07 Oct 2020 09:29:12

US3342200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 11:00:19

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:28:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd3c3a384-d8f8-4078-b06b-72927dff565f'	System	07 Oct 2020 09:29:12
User entered 'No (N)'	System	07 Oct 2020 09:29:12

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:29:10', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd3c3a384-d8f8-4078-b06b-72927dff565f'	System	07 Oct 2020 09:29:12
User entered '07 Oct 2020 04:29'	System	07 Oct 2020 09:29:12

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 16:25:19



US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:38:38', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9d3b31a0-ca9b-4286-88ef-07f6b1c5a2c6'	System	30 Sep 2020 16:38:57
User entered 'None (1)'	System	30 Sep 2020 16:38:57

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:00:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:38:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9d3b31a0-ca9b-4286-88ef-07f6b1c5a2c6'	System	30 Sep 2020 16:38:57
User entered 'No (N)'	System	30 Sep 2020 16:38:57

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:00:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:38:45', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9d3b31a0-ca9b-4286-88ef-07f6b1c5a2c6'	System	30 Sep 2020 16:38:57
User entered 'No (N)'	System	30 Sep 2020 16:38:57

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:38:50', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9d3b31a0-ca9b-4286-88ef-07f6b1c5a2c6'	System	30 Sep 2020 16:38:57
User entered 'None (1)'	System	30 Sep 2020 16:38:57

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:38:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9d3b31a0-ca9b-4286-88ef-07f6b1c5a2c6'	System	30 Sep 2020 16:38:57
User entered '30 Sep 2020 11:38'	System	30 Sep 2020 16:38:57

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:19'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 13:49'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 16:25:19



US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:41:34', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3e132107-0b91-41c8-8c29-ca920531bd22'	System	01 Oct 2020 11:41:51
User entered 'None (1)'	System	01 Oct 2020 11:41:51

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 11:00:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:41:38', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3e132107-0b91-41c8-8c29-ca920531bd22'	System	01 Oct 2020 11:41:51
User entered 'No (N)'	System	01 Oct 2020 11:41:51

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 11:00:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:41:40', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3e132107-0b91-41c8-8c29-ca920531bd22'	System	01 Oct 2020 11:41:51
User entered 'No (N)'	System	01 Oct 2020 11:41:51

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:41:46', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3e132107-0b91-41c8-8c29-ca920531bd22'	System	01 Oct 2020 11:41:51
User entered 'None (1)'	System	01 Oct 2020 11:41:51

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:41:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3e132107-0b91-41c8-8c29-ca920531bd22'	System	01 Oct 2020 11:41:51
User entered '01 Oct 2020 06:41'	System	01 Oct 2020 11:41:51

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 14:44'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 2'	System	30 Sep 2020 16:25:19



US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:01:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '30f1bc9b-967b-49f3-96fa-451ab6622ce7'	System	01 Oct 2020 17:01:49
User entered 'None (1)'	System	01 Oct 2020 17:01:49

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:00:19

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:00:57', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '30f1bc9b-967b-49f3-96fa-451ab6622ce7'	System	01 Oct 2020 17:01:49
User entered 'No (N)'	System	01 Oct 2020 17:01:49

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:00:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:01:04', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '30f1bc9b-967b-49f3-96fa-451ab6622ce7' User entered 'No (N)'	System	01 Oct 2020 17:01:49
	System	01 Oct 2020 17:01:49

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:01:07', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '30f1bc9b-967b-49f3-96fa-451ab6622ce7'	System	01 Oct 2020 17:01:49
User entered 'None (1)'	System	01 Oct 2020 17:01:49

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:01:11', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '30f1bc9b-967b-49f3-96fa-451ab6622ce7' User entered '01 Oct 2020 12:01'	System	01 Oct 2020 17:01:49
	System	01 Oct 2020 17:01:49

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 3'	System	30 Sep 2020 16:25:19



US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:03:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0181fe75-51ad-4bad-8b89-1a7ae2f4eb5d' User entered 'None (1)'	System	02 Oct 2020 17:03:39
	System	02 Oct 2020 17:03:39

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 11:00:19**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:03:25', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0181fe75-51ad-4bad-8b89-1a7ae2f4eb5d'	System	02 Oct 2020 17:03:39
User entered 'No (N)'	System	02 Oct 2020 17:03:39

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 11:00:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:03:28', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0181fe75-51ad-4bad-8b89-1a7ae2f4eb5d'	System	02 Oct 2020 17:03:39
User entered 'No (N)'	System	02 Oct 2020 17:03:39

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:03:31', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0181fe75-51ad-4bad-8b89-1a7ae2f4eb5d' User entered 'None (1)'	System	02 Oct 2020 17:03:39
	System	02 Oct 2020 17:03:39

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:03:34', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0181fe75-51ad-4bad-8b89-1a7ae2f4eb5d' User entered '02 Oct 2020 12:03'	System	02 Oct 2020 17:03:39
	System	02 Oct 2020 17:03:39

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 4'	System	30 Sep 2020 16:25:19



US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:02:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2937f7fc-cfa1-4f0f-a595-f72c1fd99368'	System	04 Oct 2020 12:03:21
User entered 'None (1)'	System	04 Oct 2020 12:03:21

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:00:19

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:02:57', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2937f7fc-cfa1-4f0f-a595-f72c1fd99368' User entered 'No (N)'	System	04 Oct 2020 12:03:21

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:00:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:03:08', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2937f7fc-cfa1-4f0f-a595-f72c1fd99368'	System	04 Oct 2020 12:03:21
User entered 'No (N)'	System	04 Oct 2020 12:03:21

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:03:13', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2937f7fc-cfa1-4f0f-a595-f72c1fd99368' User entered 'None (1)'	System	04 Oct 2020 12:03:21

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:03:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2937f7fc-cfa1-4f0f-a595-f72c1fd99368' User entered '04 Oct 2020 07:03'	System	04 Oct 2020 12:03:21
	System	04 Oct 2020 12:03:21

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 5'	System	30 Sep 2020 16:25:19



US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:34:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd5d1c7de-524c-4c8c-9691-8ee069b3d406'	System	04 Oct 2020 17:34:35
User entered 'None (1)'	System	04 Oct 2020 17:34:35

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:00:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:34:24', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd5d1c7de-524c-4c8c-9691-8ee069b3d406'	System	04 Oct 2020 17:34:35
User entered 'No (N)'	System	04 Oct 2020 17:34:35

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:00:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:34:27', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd5d1c7de-524c-4c8c-9691-8ee069b3d406'	System	04 Oct 2020 17:34:35
User entered 'No (N)'	System	04 Oct 2020 17:34:35

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:34:31', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd5d1c7de-524c-4c8c-9691-8ee069b3d406'	System	04 Oct 2020 17:34:35
User entered 'None (1)'	System	04 Oct 2020 17:34:35

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:34:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd5d1c7de-524c-4c8c-9691-8ee069b3d406'	System	04 Oct 2020 17:34:35
User entered '04 Oct 2020 12:34'	System	04 Oct 2020 17:34:35

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 6'	System	30 Sep 2020 16:25:19



US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:35:31', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c96a5b0d-b5f9-44a0-abb6-2d4cee58267b' User entered 'None (1)'	System	06 Oct 2020 07:36:19
	System	06 Oct 2020 07:36:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:00:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:35:59', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c96a5b0d-b5f9-44a0-abb6-2d4cee58267b' User entered 'No (N)'	System	06 Oct 2020 07:36:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:00:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:36:04', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c96a5b0d-b5f9-44a0-abb6-2d4cee58267b' User entered 'No (N)'	System	06 Oct 2020 07:36:19

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:36:13', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c96a5b0d-b5f9-44a0-abb6-2d4cee58267b' User entered 'None (1)'	System	06 Oct 2020 07:36:19
	System	06 Oct 2020 07:36:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:36:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c96a5b0d-b5f9-44a0-abb6-2d4cee58267b' User entered '06 Oct 2020 02:36'	System	06 Oct 2020 07:36:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 7'	System	30 Sep 2020 16:25:19



US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:29:15', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f1894783-933b-42bb-8bc1-399cf094aed8'	System	07 Oct 2020 09:29:39
User entered 'None (1)'	System	07 Oct 2020 09:29:39

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:00:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:29:18', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f1894783-933b-42bb-8bc1-399cf094aed8'	System	07 Oct 2020 09:29:39
User entered 'No (N)'	System	07 Oct 2020 09:29:39

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:00:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:29:20', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f1894783-933b-42bb-8bc1-399cf094aed8'	System	07 Oct 2020 09:29:39
User entered 'No (N)'	System	07 Oct 2020 09:29:39

US3342200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:29:27', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f1894783-933b-42bb-8bc1-399cf094aed8'	System	07 Oct 2020 09:29:39
User entered 'None (1)'	System	07 Oct 2020 09:29:39

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:29:32', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f1894783-933b-42bb-8bc1-399cf094aed8' User entered '07 Oct 2020 04:29'	System	07 Oct 2020 09:29:39
	System	07 Oct 2020 09:29:39

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 16:25:19



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:39:04', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fc29d477-7150-478f-8b70-5dbfb835a9ba' User entered 'None (0)'	System	30 Sep 2020 16:43:48
	System	30 Sep 2020 16:43:48

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:39:07', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fc29d477-7150-478f-8b70-5dbfb835a9ba' User entered 'None (0)'	System	30 Sep 2020 16:43:48
	System	30 Sep 2020 16:43:48

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:39:09', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fc29d477-7150-478f-8b70-5dbfb835a9ba' User entered 'None (0)'	System	30 Sep 2020 16:43:48
	System	30 Sep 2020 16:43:48

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:39:27', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fc29d477-7150-478f-8b70-5dbfb835a9ba' User entered 'None (0)'	System	30 Sep 2020 16:43:48
	System	30 Sep 2020 16:43:48

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:43:06', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fc29d477-7150-478f-8b70-5dbfb835a9ba' User entered 'None (0)'	System	30 Sep 2020 16:43:48
	System	30 Sep 2020 16:43:48

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:43:09', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fc29d477-7150-478f-8b70-5dbfb835a9ba' User entered 'None (0)'	System	30 Sep 2020 16:43:48
	System	30 Sep 2020 16:43:48

US3342200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:43:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fc29d477-7150-478f-8b70-5dbfb835a9ba'	System	30 Sep 2020 16:43:48
User entered 'No (N)'	System	30 Sep 2020 16:43:48

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-09-30T11:43:46', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fc29d477-7150-478f-8b70-5dbfb835a9ba' User entered '30 Sep 2020 11:43'	System	30 Sep 2020 16:43:48
	System	30 Sep 2020 16:43:48



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:19'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 13:49'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:41:55', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7f872140-2480-4ed0-a506-059986fb98c4' User entered 'None (0)'	System	01 Oct 2020 11:43:00
	System	01 Oct 2020 11:43:00

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:42:05', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7f872140-2480-4ed0-a506-059986fb98c4'	System	01 Oct 2020 11:43:00
User entered 'No interference with activity (1)'	System	01 Oct 2020 11:43:00

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:42:17', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7f872140-2480-4ed0-a506-059986fb98c4'	System	01 Oct 2020 11:43:00
User entered 'No interference with activity (1)'	System	01 Oct 2020 11:43:00

US3342200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:00:19

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:42:43', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7f872140-2480-4ed0-a506-059986fb98c4'	System	01 Oct 2020 11:43:00
User entered 'No interference with activity (1)'	System	01 Oct 2020 11:43:00

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:42:45', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7f872140-2480-4ed0-a506-059986fb98c4'	System	01 Oct 2020 11:43:00
User entered 'None (0)'	System	01 Oct 2020 11:43:00



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:42:51', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7f872140-2480-4ed0-a506-059986fb98c4' User entered 'None (0)'	System	01 Oct 2020 11:43:00

US3342200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:42:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7f872140-2480-4ed0-a506-059986fb98c4'	System	01 Oct 2020 11:43:00
User entered 'No (N)'	System	01 Oct 2020 11:43:00

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T06:42:57', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7f872140-2480-4ed0-a506-059986fb98c4' User entered '01 Oct 2020 06:42'	System	01 Oct 2020 11:43:00

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 14:44'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 2'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 11:00:19**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:01:19', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '61b3a620-7b69-4a68-920a-5138e751d577'	System	01 Oct 2020 17:03:13
User entered 'None (0)'	System	01 Oct 2020 17:03:13

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 11:00:19**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:01:29', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '61b3a620-7b69-4a68-920a-5138e751d577'	System	01 Oct 2020 17:03:13
User entered 'Some interference with activity (2)'	System	01 Oct 2020 17:03:13



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 11:00:19**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:01:34', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '61b3a620-7b69-4a68-920a-5138e751d577'	System	01 Oct 2020 17:03:13
User entered 'None (0)'	System	01 Oct 2020 17:03:13

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 11:00:19**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:01:39', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '61b3a620-7b69-4a68-920a-5138e751d577'	System	01 Oct 2020 17:03:13
User entered 'No interference with activity (1)'	System	01 Oct 2020 17:03:13

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 11:00:19**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:01:44', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '61b3a620-7b69-4a68-920a-5138e751d577'	System	01 Oct 2020 17:03:13
User entered 'None (0)'	System	01 Oct 2020 17:03:13

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 11:00:19**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:01:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '61b3a620-7b69-4a68-920a-5138e751d577'	System	01 Oct 2020 17:03:13
User entered 'None (0)'	System	01 Oct 2020 17:03:13

US3342200

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:02:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '61b3a620-7b69-4a68-920a-5138e751d577'	System	01 Oct 2020 17:03:13
User entered 'No (N)'	System	01 Oct 2020 17:03:13

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-01T12:02:06', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '61b3a620-7b69-4a68-920a-5138e751d577'	System	01 Oct 2020 17:03:13
User entered '01 Oct 2020 12:02'	System	01 Oct 2020 17:03:13

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 16:25:19



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 3'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 11:00:19**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:03:53', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0dc3eb28-e0e0-45ea-b3cb-85d7a7367b00' User entered 'None (0)'	System	02 Oct 2020 17:05:53
	System	02 Oct 2020 17:05:53

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 11:00:19**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:03:59', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0dc3eb28-e0e0-45ea-b3cb-85d7a7367b00' User entered 'None (0)'	System	02 Oct 2020 17:05:53
	System	02 Oct 2020 17:05:53

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 11:00:19**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:04:26', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0dc3eb28-e0e0-45ea-b3cb-85d7a7367b00'	System	02 Oct 2020 17:05:53
User entered 'None (0)'	System	02 Oct 2020 17:05:53

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 11:00:19**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:04:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0dc3eb28-e0e0-45ea-b3cb-85d7a7367b00'	System	02 Oct 2020 17:05:53
User entered 'Some interference with activity (2)'	System	02 Oct 2020 17:05:53

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 11:00:19**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:04:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0dc3eb28-e0e0-45ea-b3cb-85d7a7367b00' User entered 'None (0)'	System	02 Oct 2020 17:05:53

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 11:00:19**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:04:44', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0dc3eb28-e0e0-45ea-b3cb-85d7a7367b00' User entered 'None (0)'	System	02 Oct 2020 17:05:53
	System	02 Oct 2020 17:05:53

US3342200

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:04:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0dc3eb28-e0e0-45ea-b3cb-85d7a7367b00'	System	02 Oct 2020 17:05:53
User entered 'No (N)'	System	02 Oct 2020 17:05:53



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-02T12:04:52', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0dc3eb28-e0e0-45ea-b3cb-85d7a7367b00' User entered '02 Oct 2020 12:04'	System	02 Oct 2020 17:05:53
	System	02 Oct 2020 17:05:53

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 4'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 11:00:19**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:03:23', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a872d402-7e83-4975-b197-c55c377a2489'	System	04 Oct 2020 12:04:45
User entered 'None (0)'	System	04 Oct 2020 12:04:45

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 11:00:19**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:03:26', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a872d402-7e83-4975-b197-c55c377a2489' User entered 'None (0)'	System	04 Oct 2020 12:04:45
	System	04 Oct 2020 12:04:45

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 11:00:19**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:03:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a872d402-7e83-4975-b197-c55c377a2489'	System	04 Oct 2020 12:04:45
User entered 'No interference with activity (1)'	System	04 Oct 2020 12:04:45

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 11:00:19**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:03:43', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a872d402-7e83-4975-b197-c55c377a2489'	System	04 Oct 2020 12:04:45
User entered 'Some interference with activity (2)'	System	04 Oct 2020 12:04:45



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 11:00:19**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:03:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a872d402-7e83-4975-b197-c55c377a2489' User entered 'None (0)'	System	04 Oct 2020 12:04:45

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 11:00:19**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:04:29', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a872d402-7e83-4975-b197-c55c377a2489' User entered 'None (0)'	System	04 Oct 2020 12:04:45
	System	04 Oct 2020 12:04:45

US3342200

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:04:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a872d402-7e83-4975-b197-c55c377a2489'	System	04 Oct 2020 12:04:45
User entered 'No (N)'	System	04 Oct 2020 12:04:45

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T07:04:43', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a872d402-7e83-4975-b197-c55c377a2489' User entered '04 Oct 2020 07:04'	System	04 Oct 2020 12:04:45
	System	04 Oct 2020 12:04:45

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 5'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 11:00:19**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:34:38', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fe8fd985-d60d-4bf6-8466-785c6a31d0ae' User entered 'None (0)'	System	04 Oct 2020 17:35:14
	System	04 Oct 2020 17:35:14



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 11:00:19**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:34:44', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fe8fd985-d60d-4bf6-8466-785c6a31d0ae'	System	04 Oct 2020 17:35:14
User entered 'No interference with activity (1)'	System	04 Oct 2020 17:35:14

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 11:00:19**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:34:52', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fe8fd985-d60d-4bf6-8466-785c6a31d0ae' User entered 'None (0)'	System	04 Oct 2020 17:35:14
	System	04 Oct 2020 17:35:14

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 11:00:19**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:34:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fe8fd985-d60d-4bf6-8466-785c6a31d0ae'	System	04 Oct 2020 17:35:14
User entered 'Some interference with activity (2)'	System	04 Oct 2020 17:35:14

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 11:00:19**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:35:01', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fe8fd985-d60d-4bf6-8466-785c6a31d0ae' User entered 'None (0)'	System	04 Oct 2020 17:35:14
	System	04 Oct 2020 17:35:14

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 11:00:19**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:35:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fe8fd985-d60d-4bf6-8466-785c6a31d0ae' User entered 'None (0)'	System	04 Oct 2020 17:35:14

US3342200

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:35:05', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fe8fd985-d60d-4bf6-8466-785c6a31d0ae' User entered 'No (N)'	System	04 Oct 2020 17:35:14
	System	04 Oct 2020 17:35:14

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-04T12:35:08', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fe8fd985-d60d-4bf6-8466-785c6a31d0ae' User entered '04 Oct 2020 12:35'	System	04 Oct 2020 17:35:14
	System	04 Oct 2020 17:35:14

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 16:25:19



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 6'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 11:00:19**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:36:27', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3d250f40-9ada-4174-ad1d-0ff2e26c79ca' User entered 'None (0)'	System	06 Oct 2020 07:37:46

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 11:00:19**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:36:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3d250f40-9ada-4174-ad1d-0ff2e26c79ca'	System	06 Oct 2020 07:37:46
User entered 'Some interference with activity (2)'	System	06 Oct 2020 07:37:46

US3342200

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:00:19

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:36:59', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3d250f40-9ada-4174-ad1d-0ff2e26c79ca'	System	06 Oct 2020 07:37:46
User entered 'Some interference with activity (2)'	System	06 Oct 2020 07:37:46

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 11:00:19**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:37:10', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3d250f40-9ada-4174-ad1d-0ff2e26c79ca'	System	06 Oct 2020 07:37:46
User entered 'Some interference with activity (2)'	System	06 Oct 2020 07:37:46

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 11:00:19**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:37:18', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3d250f40-9ada-4174-ad1d-0ff2e26c79ca' User entered 'None (0)'	System	06 Oct 2020 07:37:46

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 11:00:19**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:37:26', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3d250f40-9ada-4174-ad1d-0ff2e26c79ca' User entered 'None (0)'	System	06 Oct 2020 07:37:46



US3342200

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:37:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3d250f40-9ada-4174-ad1d-0ff2e26c79ca'	System	06 Oct 2020 07:37:46
User entered 'No (N)'	System	06 Oct 2020 07:37:46

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-06T02:37:40', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3d250f40-9ada-4174-ad1d-0ff2e26c79ca' User entered '06 Oct 2020 02:37'	System	06 Oct 2020 07:37:46
	System	06 Oct 2020 07:37:46

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 16:25:19
User entered 'Day 7'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 11:00:19**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:29:40', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '11a79136-6434-4090-8b97-3f3306618f76'	System	07 Oct 2020 09:30:27
User entered 'None (0)'	System	07 Oct 2020 09:30:27

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 11:00:19**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:29:47', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '11a79136-6434-4090-8b97-3f3306618f76'	System	07 Oct 2020 09:30:27
User entered 'Some interference with activity (2)'	System	07 Oct 2020 09:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:00:19

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:29:52', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '11a79136-6434-4090-8b97-3f3306618f76'	System	07 Oct 2020 09:30:27
User entered 'Some interference with activity (2)'	System	07 Oct 2020 09:30:27



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 11:00:19**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:29:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '11a79136-6434-4090-8b97-3f3306618f76'	System	07 Oct 2020 09:30:27
User entered 'Some interference with activity (2)'	System	07 Oct 2020 09:30:27

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 11:00:19**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:30:04', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '11a79136-6434-4090-8b97-3f3306618f76'	System	07 Oct 2020 09:30:27
User entered 'None (0)'	System	07 Oct 2020 09:30:27

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 11:00:19**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:30:07', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '11a79136-6434-4090-8b97-3f3306618f76'	System	07 Oct 2020 09:30:27
User entered 'None (0)'	System	07 Oct 2020 09:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:30:15', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '11a79136-6434-4090-8b97-3f3306618f76'	System	07 Oct 2020 09:30:27
User entered 'No (N)'	System	07 Oct 2020 09:30:27

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T04:30:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '11a79136-6434-4090-8b97-3f3306618f76'	System	07 Oct 2020 09:30:27
User entered '07 Oct 2020 04:30'	System	07 Oct 2020 09:30:27

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 16:25:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 07:37:46
User entered 'Day 8'	System	06 Oct 2020 07:37:46



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T16:48:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fe01478b-ecfe-49b4-a874-b565657a0dbb'	System	07 Oct 2020 21:48:31
User entered 'No interference with activity (1)'	System	07 Oct 2020 21:48:31

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T16:48:27', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fe01478b-ecfe-49b4-a874-b565657a0dbb'	System	07 Oct 2020 21:48:31
User entered '07 Oct 2020 16:48'	System	07 Oct 2020 21:48:31

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 07:37:46

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 07:37:46

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 09:30:27
User entered 'Day 9'	System	07 Oct 2020 09:30:27

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-08T12:00:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '50ad4aff-05da-472b-b4d3-c4de1d88957b'	System	08 Oct 2020 17:00:27
User entered 'Some interference with activity (2)'	System	08 Oct 2020 17:00:27

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-08T12:00:20', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '50ad4aff-05da-472b-b4d3-c4de1d88957b' User entered '08 Oct 2020 12:00'	System	08 Oct 2020 17:00:27
	System	08 Oct 2020 17:00:27

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 09:30:27



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 09:30:27

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(10)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 21:48:31
User entered 'Day 10'	System	07 Oct 2020 21:48:31

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(10)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-09T12:14:37', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '34596b5e-bb9e-48fe-9901-df55c0ec635c'	System	09 Oct 2020 17:14:47
User entered 'No interference with activity (1)'	System	09 Oct 2020 17:14:47

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(10)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-09T12:14:43', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '34596b5e-bb9e-48fe-9901-df55c0ec635c' User entered '09 Oct 2020 12:14'	System	09 Oct 2020 17:14:47
	System	09 Oct 2020 17:14:47

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(10)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 21:48:31

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(10)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 21:48:31

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(11)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 17:00:27
User entered 'Day 11'	System	08 Oct 2020 17:00:27

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(11)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-10T12:04:02', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9c72b484-b9ee-4f5f-9014-1838b55c550a'	System	10 Oct 2020 17:04:11
User entered 'Some interference with activity (2)'	System	10 Oct 2020 17:04:11



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(11)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-10T12:04:07', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9c72b484-b9ee-4f5f-9014-1838b55c550a' User entered '10 Oct 2020 12:04'	System	10 Oct 2020 17:04:11
	System	10 Oct 2020 17:04:11

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(11)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 17:00:27

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(11)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 17:00:27

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(12)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 17:14:47
User entered 'Day 12'	System	09 Oct 2020 17:14:47

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(12)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-11T17:26:39', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0fe06727-7158-4a7a-8dd6-55fcfeae94df'	System	11 Oct 2020 22:26:46
User entered 'No interference with activity (1)'	System	11 Oct 2020 22:26:46

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(12)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-11T17:26:42', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0fe06727-7158-4a7a-8dd6-55fcfeae94df' User entered '11 Oct 2020 17:26'	System	11 Oct 2020 22:26:46
	System	11 Oct 2020 22:26:46

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(12)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 17:14:47

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(12)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 17:14:47



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(13)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Oct 2020 17:04:11
User entered 'Day 13'	System	10 Oct 2020 17:04:11

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(13)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-12T16:02:11', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dee9ec37-361a-4c46-867d-ccdc9ceccc58'	System	12 Oct 2020 21:02:18
User entered 'Some interference with activity (2)'	System	12 Oct 2020 21:02:18

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(13)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-12T16:02:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dee9ec37-361a-4c46-867d-ccdc9ceccc58' User entered '12 Oct 2020 16:02'	System	12 Oct 2020 21:02:18
	System	12 Oct 2020 21:02:18

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(13)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	10 Oct 2020 17:04:11

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(13)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	10 Oct 2020 17:04:11

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(14)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Oct 2020 22:26:46
User entered 'Day 14'	System	11 Oct 2020 22:26:46

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(14)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T06:26:19', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '569524e1-d30e-43cd-a0e3-a2e83b872f31'	System	14 Oct 2020 11:26:26
User entered 'Some interference with activity (2)'	System	14 Oct 2020 11:26:26

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(14)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T06:26:23', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '569524e1-d30e-43cd-a0e3-a2e83b872f31' User entered '14 Oct 2020 06:26'	System	14 Oct 2020 11:26:26
	System	14 Oct 2020 11:26:26



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(14)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	11 Oct 2020 22:26:46

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(14)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	11 Oct 2020 22:26:46

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(15)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 21:02:18
User entered 'Day 15'	System	12 Oct 2020 21:02:18

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(15)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T13:40:45', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '986e6935-bd0c-4f50-9ffc-f066ccc917e5'	System	14 Oct 2020 18:40:52
User entered 'No interference with activity (1)'	System	14 Oct 2020 18:40:52

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(15)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T13:40:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '986e6935-bd0c-4f50-9ffc-f066ccc917e5' User entered '14 Oct 2020 13:40'	System	14 Oct 2020 18:40:52

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(15)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 21:02:18

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(15)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 21:02:18

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(16)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 11:26:26
User entered 'Day 16'	System	14 Oct 2020 11:26:26



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(16)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T02:16:44', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a16f757d-45d6-43ba-9c4a-ae400b681616'	System	16 Oct 2020 07:16:52
User entered 'No interference with activity (1)'	System	16 Oct 2020 07:16:52

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(16)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T02:16:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a16f757d-45d6-43ba-9c4a-ae400b681616' User entered '16 Oct 2020 02:16'	System	16 Oct 2020 07:16:52
	System	16 Oct 2020 07:16:52

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(16)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 11:26:26

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(16)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 11:26:26

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(17)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 18:40:52
User entered 'Day 17'	System	14 Oct 2020 18:40:52

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(17)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T12:08:26', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3cdecbl1a-7eea-405a-8d7d-6906958efe1f' User entered 'None (0)'	System	16 Oct 2020 17:08:35
	System	16 Oct 2020 17:08:35

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(17)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T12:08:31', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3cdecbl1a-7eea-405a-8d7d-6906958efe1f' User entered '16 Oct 2020 12:08'	System	16 Oct 2020 17:08:35
	System	16 Oct 2020 17:08:35

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(17)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 18:40:52



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(17)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 18:40:52

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 07:37:46
User entered 'Day 8'	System	06 Oct 2020 07:37:46

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 26 Nov 2020 11:00:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T16:48:43', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '15723c3d-fb3b-4cdb-83ba-a997cdd2e3df'	System	07 Oct 2020 21:48:50
User entered 'No interference with activity (1)'	System	07 Oct 2020 21:48:50

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T16:48:47', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '15723c3d-fb3b-4cdb-83ba-a997cdd2e3df' User entered '07 Oct 2020 16:48'	System	07 Oct 2020 21:48:50
	System	07 Oct 2020 21:48:50

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 07:37:46

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 07:37:46

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(9)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 09:30:27
User entered 'Day 9'	System	07 Oct 2020 09:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(9)

Generated On: 26 Nov 2020 11:00:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-08T12:00:25', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f7ef84c6-6222-42b0-86aa-4639b335601b'	System	08 Oct 2020 17:00:47
User entered 'No interference with activity (1)'	System	08 Oct 2020 17:00:47



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(9)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-08T12:00:28', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f7ef84c6-6222-42b0-86aa-4639b335601b' User entered '08 Oct 2020 12:00'	System	08 Oct 2020 17:00:47
	System	08 Oct 2020 17:00:47

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(9)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 09:30:27

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(9)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 09:30:27

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(10)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 21:48:50
User entered 'Day 10'	System	07 Oct 2020 21:48:50

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(10)

Generated On: 26 Nov 2020 11:00:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-09T12:14:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ca8d0529-fdee-447a-889e-79fafc360864'	System	09 Oct 2020 17:15:06
User entered 'No interference with activity (1)'	System	09 Oct 2020 17:15:06

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(10)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-09T12:15:01', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ca8d0529-fdee-447a-889e-79fafc360864' User entered '09 Oct 2020 12:15'	System	09 Oct 2020 17:15:06
	System	09 Oct 2020 17:15:06

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(10)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 21:48:50

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(10)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 21:48:50



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(11)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 17:00:47
User entered 'Day 11'	System	08 Oct 2020 17:00:47

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(11)

Generated On: 26 Nov 2020 11:00:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-10T12:04:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3519342f-8f58-4f80-b9f0-6f7826f5d178'	System	10 Oct 2020 17:04:22
User entered 'Some interference with activity (2)'	System	10 Oct 2020 17:04:22

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(11)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-10T12:04:19', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3519342f-8f58-4f80-b9f0-6f7826f5d178' User entered '10 Oct 2020 12:04'	System	10 Oct 2020 17:04:22
	System	10 Oct 2020 17:04:22

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(11)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 17:00:47

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(11)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 17:00:47

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(12)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 17:15:06
User entered 'Day 12'	System	09 Oct 2020 17:15:06

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(12)

Generated On: 26 Nov 2020 11:00:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-11T17:26:47', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '5e50f26c-9da8-4488-ab28-e017d57040c9'	System	11 Oct 2020 22:26:52
User entered 'No interference with activity (1)'	System	11 Oct 2020 22:26:52

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(12)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-11T17:26:50', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '5e50f26c-9da8-4488-ab28-e017d57040c9' User entered '11 Oct 2020 17:26'	System	11 Oct 2020 22:26:52
	System	11 Oct 2020 22:26:52



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(12)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 17:15:06

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(12)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 17:15:06

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(13)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Oct 2020 17:04:22
User entered 'Day 13'	System	10 Oct 2020 17:04:22

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(13)

Generated On: 26 Nov 2020 11:00:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-12T16:02:24', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'da303063-927a-43b4-85f8-591e7e3463ac'	System	12 Oct 2020 21:02:30
User entered 'No interference with activity (1)'	System	12 Oct 2020 21:02:30

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(13)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-12T16:02:27', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'da303063-927a-43b4-85f8-591e7e3463ac' User entered '12 Oct 2020 16:02'	System	12 Oct 2020 21:02:30
	System	12 Oct 2020 21:02:30

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(13)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	10 Oct 2020 17:04:22

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(13)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	10 Oct 2020 17:04:22

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(14)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Oct 2020 22:26:52
User entered 'Day 14'	System	11 Oct 2020 22:26:52



US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(14)

Generated On: 26 Nov 2020 11:00:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T06:26:28', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '74a6eefb-25d8-4180-a9bc-b2848e26fe55'	System	14 Oct 2020 11:26:35
User entered 'No interference with activity (1)'	System	14 Oct 2020 11:26:35

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(14)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T06:26:32', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '74a6eefb-25d8-4180-a9bc-b2848e26fe55' User entered '14 Oct 2020 06:26'	System	14 Oct 2020 11:26:35
	System	14 Oct 2020 11:26:35

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(14)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	11 Oct 2020 22:26:52

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(14)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	11 Oct 2020 22:26:52

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(15)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 21:02:30
User entered 'Day 15'	System	12 Oct 2020 21:02:30

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(15)

Generated On: 26 Nov 2020 11:00:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T13:40:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7fb59d8e-bf3d-41c1-9520-afabe1a8434c'	System	14 Oct 2020 18:40:59
User entered 'No interference with activity (1)'	System	14 Oct 2020 18:40:59

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(15)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T13:40:56', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7fb59d8e-bf3d-41c1-9520-afabe1a8434c' User entered '14 Oct 2020 13:40'	System	14 Oct 2020 18:40:59
	System	14 Oct 2020 18:40:59

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(15)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 21:02:30



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(15)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 21:02:30

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(16)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 11:26:35
User entered 'Day 16'	System	14 Oct 2020 11:26:35

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(16)

Generated On: 26 Nov 2020 11:00:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T02:16:55', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd9304d65-e7e8-4f50-bda3-a19811369314'	System	16 Oct 2020 07:17:00
User entered 'No interference with activity (1)'	System	16 Oct 2020 07:17:00

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(16)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T02:16:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd9304d65-e7e8-4f50-bda3-a19811369314' User entered '16 Oct 2020 02:16'	System	16 Oct 2020 07:17:00
	System	16 Oct 2020 07:17:00

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(16)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 11:26:35

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(16)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 11:26:35

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(17)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 18:40:59
User entered 'Day 17'	System	14 Oct 2020 18:40:59

US3342200

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(17)

Generated On: 26 Nov 2020 11:00:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T12:08:35', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9ba3081d-ce42-4e7d-8985-a621d4b00f61' User entered 'None (0)'	System	16 Oct 2020 17:08:42



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(17)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T12:08:38', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9ba3081d-ce42-4e7d-8985-a621d4b00f61' User entered '16 Oct 2020 12:08'	System	16 Oct 2020 17:08:42
	System	16 Oct 2020 17:08:42

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(17)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 18:40:59

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(17)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 18:40:59

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 07:37:46
User entered 'Day 8'	System	06 Oct 2020 07:37:46

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 26 Nov 2020 11:00:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T16:48:52', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2a09029f-574b-4a93-ba96-c4361624c270'	System	07 Oct 2020 21:48:59
User entered 'Some interference with activity (2)'	System	07 Oct 2020 21:48:59

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T16:48:56', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2a09029f-574b-4a93-ba96-c4361624c270' User entered '07 Oct 2020 16:48'	System	07 Oct 2020 21:48:59
	System	07 Oct 2020 21:48:59

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 07:37:46

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 07:37:46



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 09:30:27
User entered 'Day 9'	System	07 Oct 2020 09:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(9)

Generated On: 26 Nov 2020 11:00:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-08T12:00:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '955d25dc-9925-431b-b588-28bc7c629aa9'	System	08 Oct 2020 17:00:50
User entered 'Some interference with activity (2)'	System	08 Oct 2020 17:00:50

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-08T12:00:35', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '955d25dc-9925-431b-b588-28bc7c629aa9' User entered '08 Oct 2020 12:00'	System	08 Oct 2020 17:00:50
	System	08 Oct 2020 17:00:50

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 09:30:27

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 09:30:27

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(10)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 21:48:59
User entered 'Day 10'	System	07 Oct 2020 21:48:59

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(10)

Generated On: 26 Nov 2020 11:00:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-09T12:15:10', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '92c1c0f8-adcb-477e-a77a-b3396eb33f58'	System	09 Oct 2020 17:15:19
User entered 'Some interference with activity (2)'	System	09 Oct 2020 17:15:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(10)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-09T12:15:14', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '92c1c0f8-adcb-477e-a77a-b3396eb33f58' User entered '09 Oct 2020 12:15'	System	09 Oct 2020 17:15:19
	System	09 Oct 2020 17:15:19



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(10)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 21:48:59

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(10)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 21:48:59

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(11)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 17:00:50
User entered 'Day 11'	System	08 Oct 2020 17:00:50

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(11)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-10T12:04:23', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7b4c8916-af48-4436-acc7-b1e9dc6880f1'	System	10 Oct 2020 17:04:28
User entered 'Some interference with activity (2)'	System	10 Oct 2020 17:04:28

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(11)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-10T12:04:26', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7b4c8916-af48-4436-acc7-b1e9dc6880f1' User entered '10 Oct 2020 12:04'	System	10 Oct 2020 17:04:28
	System	10 Oct 2020 17:04:28

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(11)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 17:00:50

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(11)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 17:00:50

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(12)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 17:15:19
User entered 'Day 12'	System	09 Oct 2020 17:15:19



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(12)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-11T17:26:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3f950398-d7b3-48ad-9351-fbae712b66fc'	System	11 Oct 2020 22:27:01
User entered 'Some interference with activity (2)'	System	11 Oct 2020 22:27:01

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(12)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-11T17:26:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3f950398-d7b3-48ad-9351-fbae712b66fc' User entered '11 Oct 2020 17:26'	System	11 Oct 2020 22:27:01
	System	11 Oct 2020 22:27:01

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(12)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 17:15:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(12)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 17:15:19

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(13)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Oct 2020 17:04:28
User entered 'Day 13'	System	10 Oct 2020 17:04:28

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(13)

Generated On: 26 Nov 2020 11:00:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-12T16:02:35', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1b65ab93-652a-4ccf-ab90-48d8fe91d59b'	System	12 Oct 2020 21:02:42
User entered 'Some interference with activity (2)'	System	12 Oct 2020 21:02:42

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(13)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-12T16:02:38', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1b65ab93-652a-4ccf-ab90-48d8fe91d59b' User entered '12 Oct 2020 16:02'	System	12 Oct 2020 21:02:42
	System	12 Oct 2020 21:02:42

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(13)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	10 Oct 2020 17:04:28



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(13)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	10 Oct 2020 17:04:28

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(14)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Oct 2020 22:27:01
User entered 'Day 14'	System	11 Oct 2020 22:27:01

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(14)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T06:26:37', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '62d9ea7a-d32e-439e-90b1-edbc061475d'	System	14 Oct 2020 11:26:43
User entered 'Some interference with activity (2)'	System	14 Oct 2020 11:26:43

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(14)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T06:26:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '62d9ea7a-d32e-439e-90b1-edbc061475d' User entered '14 Oct 2020 06:26'	System	14 Oct 2020 11:26:43

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(14)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	11 Oct 2020 22:27:01

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(14)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	11 Oct 2020 22:27:01

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(15)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 21:02:42
User entered 'Day 15'	System	12 Oct 2020 21:02:42

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(15)

Generated On: 26 Nov 2020 11:00:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T13:41:02', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e9ff9e23-6a7e-4b38-95d0-6e4fff3422b7'	System	14 Oct 2020 18:41:09
User entered 'No interference with activity (1)'	System	14 Oct 2020 18:41:09



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(15)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T13:41:04', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e9ff9e23-6a7e-4b38-95d0-6e4fff3422b7' User entered '14 Oct 2020 13:41'	System	14 Oct 2020 18:41:09
	System	14 Oct 2020 18:41:09

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(15)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 21:02:42

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(15)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 21:02:42

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(16)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 11:26:43
User entered 'Day 16'	System	14 Oct 2020 11:26:43

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(16)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T02:17:05', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '858ed4a9-5fc2-4060-8113-a1326101ae82'	System	16 Oct 2020 07:17:11
User entered 'Some interference with activity (2)'	System	16 Oct 2020 07:17:11

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(16)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T02:17:08', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '858ed4a9-5fc2-4060-8113-a1326101ae82' User entered '16 Oct 2020 02:17'	System	16 Oct 2020 07:17:11
	System	16 Oct 2020 07:17:11

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(16)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 11:26:43

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(16)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 11:26:43



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(17)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 18:41:09
User entered 'Day 17'	System	14 Oct 2020 18:41:09

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(17)

Generated On: 26 Nov 2020 11:00:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T12:08:42', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '271050a6-4944-49c4-9a0d-8ef52d377375'	System	16 Oct 2020 17:08:49
User entered 'No interference with activity (1)'	System	16 Oct 2020 17:08:49

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(17)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T12:08:44', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '271050a6-4944-49c4-9a0d-8ef52d377375' User entered '16 Oct 2020 12:08'	System	16 Oct 2020 17:08:49
	System	16 Oct 2020 17:08:49

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(17)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 18:41:09

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(17)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 18:41:09

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(18)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 07:17:11
User entered 'Day 18'	System	16 Oct 2020 07:17:11

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(18)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-17T15:00:11', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd57a0e06-e901-4385-ba24-a6f7a5f828ce'	System	17 Oct 2020 20:00:18
User entered 'Some interference with activity (2)'	System	17 Oct 2020 20:00:18

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(18)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-17T15:00:15', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd57a0e06-e901-4385-ba24-a6f7a5f828ce' User entered '17 Oct 2020 15:00'	System	17 Oct 2020 20:00:18
	System	17 Oct 2020 20:00:18



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(18)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 07:17:11

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(18)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 07:17:11

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(19)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 17:08:49
User entered 'Day 19'	System	16 Oct 2020 17:08:49

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(19)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-18T12:10:02', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '01a46dbf-52ca-4e3a-af2a-79ad63693986'	System	18 Oct 2020 17:10:07
User entered 'No interference with activity (1)'	System	18 Oct 2020 17:10:07

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(19)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-18T12:10:05', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '01a46dbf-52ca-4e3a-af2a-79ad63693986' User entered '18 Oct 2020 12:10'	System	18 Oct 2020 17:10:07
	System	18 Oct 2020 17:10:07

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(19)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 17:08:49

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(19)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 17:08:49

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(20)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Oct 2020 20:00:18
User entered 'Day 20'	System	17 Oct 2020 20:00:18



US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(20)

Generated On: 26 Nov 2020 11:00:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-19T16:38:47', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd9773d79-39a2-4603-be88-18d042f9bdfd'	System	19 Oct 2020 21:38:54
User entered 'Some interference with activity (2)'	System	19 Oct 2020 21:38:54

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(20)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-19T16:38:51', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd9773d79-39a2-4603-be88-18d042f9bdfd' User entered '19 Oct 2020 16:38'	System	19 Oct 2020 21:38:54
	System	19 Oct 2020 21:38:54

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(20)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	17 Oct 2020 20:00:18

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(20)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	17 Oct 2020 20:00:18

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(21)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	18 Oct 2020 17:10:07
User entered 'Day 21'	System	18 Oct 2020 17:10:07

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(21)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-20T12:39:11', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7a835e0c-798c-4f76-9577-37ae87501516'	System	20 Oct 2020 17:39:17
User entered 'Some interference with activity (2)'	System	20 Oct 2020 17:39:17

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(21)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-20T12:39:14', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7a835e0c-798c-4f76-9577-37ae87501516' User entered '20 Oct 2020 12:39'	System	20 Oct 2020 17:39:17
	System	20 Oct 2020 17:39:17

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(21)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	18 Oct 2020 17:10:07



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(21)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	18 Oct 2020 17:10:07

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(22)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	19 Oct 2020 21:38:54
User entered 'Day 22'	System	19 Oct 2020 21:38:54

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(22)

Generated On: 26 Nov 2020 11:00:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-21T12:04:29', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '4ea81c96-cd95-418f-9792-aaa9d7b56c79'	System	21 Oct 2020 17:04:40
User entered 'Some interference with activity (2)'	System	21 Oct 2020 17:04:40

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(22)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-21T12:04:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '4ea81c96-cd95-418f-9792-aaa9d7b56c79' User entered '21 Oct 2020 12:04'	System	21 Oct 2020 17:04:40
	System	21 Oct 2020 17:04:40

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(22)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 21:38:54

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(22)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 21:38:54

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(23)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 17:39:17
User entered 'Day 23'	System	20 Oct 2020 17:39:17

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(23)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-22T12:08:21', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '92af3dfd-03fa-4f2b-b489-236f70052ced' User entered 'Some interference with activity (2)'	System	22 Oct 2020 17:08:26



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(23)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-22T12:08:24', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '92af3dfd-03fa-4f2b-b489-236f70052ced' User entered '22 Oct 2020 12:08'	System	22 Oct 2020 17:08:26
	System	22 Oct 2020 17:08:26

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(23)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 17:39:17

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(23)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 17:39:17

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(24)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 17:04:40
User entered 'Day 24'	System	21 Oct 2020 17:04:40

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(24)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-23T12:00:21', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2aa1c910-3024-4836-8f2c-e5b1d2a8f759'	System	23 Oct 2020 17:00:29
User entered 'Some interference with activity (2)'	System	23 Oct 2020 17:00:29

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(24)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-23T12:00:25', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2aa1c910-3024-4836-8f2c-e5b1d2a8f759' User entered '23 Oct 2020 12:00'	System	23 Oct 2020 17:00:29
	System	23 Oct 2020 17:00:29

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(24)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 17:04:40

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(24)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 17:04:40



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(25)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 17:08:26
User entered 'Day 25'	System	22 Oct 2020 17:08:26

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(25)

Generated On: 26 Nov 2020 11:00:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-24T17:55:15', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '6aad7127-d1a5-4aa0-ab11-6682e06f0512'	System	24 Oct 2020 22:55:23
User entered 'No interference with activity (1)'	System	24 Oct 2020 22:55:23

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(25)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-24T17:55:21', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '6aad7127-d1a5-4aa0-ab11-6682e06f0512' User entered '24 Oct 2020 17:55'	System	24 Oct 2020 22:55:23
	System	24 Oct 2020 22:55:23

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(25)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 17:08:26

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(25)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 17:08:26

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(26)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Oct 2020 17:00:29
User entered 'Day 26'	System	23 Oct 2020 17:00:29

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(26)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-25T13:14:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3291dac1-c4ee-40c0-b405-064f1057cf15'	System	25 Oct 2020 18:14:52
User entered 'Some interference with activity (2)'	System	25 Oct 2020 18:14:52

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(26)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-25T13:14:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3291dac1-c4ee-40c0-b405-064f1057cf15' User entered '25 Oct 2020 13:14'	System	25 Oct 2020 18:14:52
	System	25 Oct 2020 18:14:52



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(26)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 17:00:29

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(26)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 17:00:29

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(27)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	24 Oct 2020 22:55:23
User entered 'Day 27'	System	24 Oct 2020 22:55:23

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(27)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-26T12:00:34', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '772e1016-76bf-40fe-8acb-bcb43b60c30c'	System	26 Oct 2020 17:01:15
User entered 'No interference with activity (1)'	System	26 Oct 2020 17:01:15

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(27)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-26T12:00:38', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '772e1016-76bf-40fe-8acb-bcb43b60c30c' User entered '26 Oct 2020 12:00'	System	26 Oct 2020 17:01:15
	System	26 Oct 2020 17:01:15

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(27)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 12:00'	System	24 Oct 2020 22:55:23

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(27)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 11:59'	System	24 Oct 2020 22:55:23

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(28)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	25 Oct 2020 18:14:52
User entered 'Day 28'	System	25 Oct 2020 18:14:52



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(28)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-27T12:15:46', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '95bd0b31-b612-466b-8381-97288e44132b'	System	27 Oct 2020 17:15:53
User entered 'Some interference with activity (2)'	System	27 Oct 2020 17:15:53

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(28)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-27T12:15:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '95bd0b31-b612-466b-8381-97288e44132b' User entered '27 Oct 2020 12:15'	System	27 Oct 2020 17:15:53
	System	27 Oct 2020 17:15:53

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(28)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 12:00'	System	25 Oct 2020 18:14:52

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(28)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 11:59'	System	25 Oct 2020 18:14:52

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(29)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	26 Oct 2020 17:01:15
User entered 'Day 29'	System	26 Oct 2020 17:01:15

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(29)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-28T13:15:01', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '836916a1-5bf0-4d88-a6ac-07d13243cb2a'	System	28 Oct 2020 18:15:07
User entered 'Some interference with activity (2)'	System	28 Oct 2020 18:15:07

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(29)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-28T13:15:04', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '836916a1-5bf0-4d88-a6ac-07d13243cb2a' User entered '28 Oct 2020 13:15'	System	28 Oct 2020 18:15:07
	System	28 Oct 2020 18:15:07

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(29)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 12:00'	System	26 Oct 2020 17:01:15



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(29)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020 11:59'	System	26 Oct 2020 17:01:15

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(30)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	27 Oct 2020 17:15:53
User entered 'Day 30'	System	27 Oct 2020 17:15:53

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(30)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-29T13:11:39', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ae0905f3-654d-46fe-81fa-faf91a5a4735'	System	29 Oct 2020 18:11:47
User entered 'Some interference with activity (2)'	System	29 Oct 2020 18:11:47

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(30)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-29T13:11:42', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ae0905f3-654d-46fe-81fa-faf91a5a4735' User entered '29 Oct 2020 13:11'	System	29 Oct 2020 18:11:47
	System	29 Oct 2020 18:11:47

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(30)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 17:15:53

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(30)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 17:15:53

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(31)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Oct 2020 18:15:07
User entered 'Day 31'	System	28 Oct 2020 18:15:07

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(31)

Generated On: 26 Nov 2020 11:00:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-30T12:00:34', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '165ab8fd-6152-43e9-8a08-e00e50374b75'	System	30 Oct 2020 17:01:16
User entered 'Some interference with activity (2)'	System	30 Oct 2020 17:01:16



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(31)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-30T12:00:39', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '165ab8fd-6152-43e9-8a08-e00e50374b75' User entered '30 Oct 2020 12:00'	System	30 Oct 2020 17:01:16
	System	30 Oct 2020 17:01:16

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(31)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 18:15:07

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(31)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 18:15:07

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(32)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	29 Oct 2020 18:11:47
User entered 'Day 32'	System	29 Oct 2020 18:11:47

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(32)

Generated On: 26 Nov 2020 11:00:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-31T16:56:53', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f7b10f83-6f47-4acd-a407-01ad216bd7c5'	System	31 Oct 2020 21:56:59
User entered 'Some interference with activity (2)'	System	31 Oct 2020 21:56:59

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(32)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-31T16:56:56', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f7b10f83-6f47-4acd-a407-01ad216bd7c5' User entered '31 Oct 2020 16:56'	System	31 Oct 2020 21:56:59
	System	31 Oct 2020 21:56:59

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(32)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Oct 2020 12:00'	System	29 Oct 2020 18:11:47

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(32)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Nov 2020 11:59'	System	29 Oct 2020 18:11:47



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(33)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Oct 2020 17:01:16
User entered 'Day 33'	System	30 Oct 2020 17:01:16

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(33)

Generated On: 26 Nov 2020 11:00:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-01T14:03:25', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fadecb0c-f7c8-488b-8c6f-3add290d3061'	System	01 Nov 2020 20:03:38
User entered 'Some interference with activity (2)'	System	01 Nov 2020 20:03:38

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(33)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-01T14:03:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fadecb0c-f7c8-488b-8c6f-3add290d3061' User entered '01 Nov 2020 14:03'	System	01 Nov 2020 20:03:38
	System	01 Nov 2020 20:03:38

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(33)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 17:01:16

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(33)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 17:01:16

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(34)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Oct 2020 21:56:59
User entered 'Day 34'	System	31 Oct 2020 21:56:59

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(34)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-02T17:31:53', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e7ab827c-c69f-4a77-bbe7-78b3357f9e3a'	System	02 Nov 2020 23:31:59
User entered 'Some interference with activity (2)'	System	02 Nov 2020 23:31:59

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(34)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-02T17:31:57', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e7ab827c-c69f-4a77-bbe7-78b3357f9e3a' User entered '02 Nov 2020 17:31'	System	02 Nov 2020 23:31:59
	System	02 Nov 2020 23:31:59



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(34)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Nov 2020 12:00'	System	31 Oct 2020 21:56:59

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(34)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Nov 2020 11:59'	System	31 Oct 2020 21:56:59

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(35)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Nov 2020 20:03:38
User entered 'Day 35'	System	01 Nov 2020 20:03:38

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(35)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-03T18:01:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7e465ac8-ed24-40b2-9bc0-99a5d06377f0'	System	04 Nov 2020 00:02:03
User entered 'Some interference with activity (2)'	System	04 Nov 2020 00:02:03

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(35)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-03T18:01:59', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7e465ac8-ed24-40b2-9bc0-99a5d06377f0' User entered '03 Nov 2020 18:01'	System	04 Nov 2020 00:02:03
	System	04 Nov 2020 00:02:03

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(35)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Nov 2020 12:00'	System	01 Nov 2020 20:03:38

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(35)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Nov 2020 11:59'	System	01 Nov 2020 20:03:38

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(36)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Nov 2020 23:31:59
User entered 'Day 36'	System	02 Nov 2020 23:31:59



US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(36)

Generated On: 26 Nov 2020 11:00:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-05T06:41:30', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '16f2f42c-9ab5-4c81-ac04-41cb1e6b9879'	System	05 Nov 2020 12:41:37
User entered 'Some interference with activity (2)'	System	05 Nov 2020 12:41:37

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(36)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-05T06:41:35', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '16f2f42c-9ab5-4c81-ac04-41cb1e6b9879' User entered '05 Nov 2020 06:41'	System	05 Nov 2020 12:41:37
	System	05 Nov 2020 12:41:37

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(36)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Nov 2020 12:00'	System	02 Nov 2020 23:31:59

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(36)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Nov 2020 11:59'	System	02 Nov 2020 23:31:59

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(37)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Nov 2020 00:02:03
User entered 'Day 37'	System	04 Nov 2020 00:02:03

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(37)

Generated On: 26 Nov 2020 11:00:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-05T12:13:31', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '83e416d9-ed53-4153-9755-ab1757d2cd5a'	System	05 Nov 2020 18:13:36
User entered 'No interference with activity (1)'	System	05 Nov 2020 18:13:36

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(37)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-05T12:13:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '83e416d9-ed53-4153-9755-ab1757d2cd5a' User entered '05 Nov 2020 12:13'	System	05 Nov 2020 18:13:36
	System	05 Nov 2020 18:13:36

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(37)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Nov 2020 12:00'	System	04 Nov 2020 00:02:03



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(37)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Nov 2020 11:59'	System	04 Nov 2020 00:02:03

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(38)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Nov 2020 12:41:37
User entered 'Day 38'	System	05 Nov 2020 12:41:37

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(38)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-07T04:41:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f1e2c6f1-cb47-43a8-b2d7-2f5139d1845a'	System	07 Nov 2020 10:41:41
User entered 'Some interference with activity (2)'	System	07 Nov 2020 10:41:41

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(38)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-07T04:41:38', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f1e2c6f1-cb47-43a8-b2d7-2f5139d1845a' User entered '07 Nov 2020 04:41'	System	07 Nov 2020 10:41:41
	System	07 Nov 2020 10:41:41

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(38)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Nov 2020 12:00'	System	05 Nov 2020 12:41:37

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(38)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Nov 2020 11:59'	System	05 Nov 2020 12:41:37

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(39)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Nov 2020 18:13:36
User entered 'Day 39'	System	05 Nov 2020 18:13:36

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(39)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-07T12:30:29', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '345d244c-116c-4aad-b80f-dea98179c269'	System	07 Nov 2020 18:30:37
User entered 'Some interference with activity (2)'	System	07 Nov 2020 18:30:37



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(39)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-07T12:30:32', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '345d244c-116c-4aad-b80f-dea98179c269' User entered '07 Nov 2020 12:30'	System	07 Nov 2020 18:30:37
	System	07 Nov 2020 18:30:37

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(39)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Nov 2020 12:00'	System	05 Nov 2020 18:13:36

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(39)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Nov 2020 11:59'	System	05 Nov 2020 18:13:36

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(40)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Nov 2020 10:41:41
User entered 'Day 40'	System	07 Nov 2020 10:41:41

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(40)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-08T12:00:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e55514fb-9a34-4c44-8fe2-380f270e81ee'	System	08 Nov 2020 18:00:54
User entered 'Some interference with activity (2)'	System	08 Nov 2020 18:00:54

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(40)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-08T12:00:52', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e55514fb-9a34-4c44-8fe2-380f270e81ee' User entered '08 Nov 2020 12:00'	System	08 Nov 2020 18:00:54
	System	08 Nov 2020 18:00:54

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(40)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Nov 2020 12:00'	System	07 Nov 2020 10:41:41

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(40)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Nov 2020 11:59'	System	07 Nov 2020 10:41:41



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(41)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Nov 2020 18:30:37
User entered 'Day 41'	System	07 Nov 2020 18:30:37

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(41)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-09T21:21:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ab73fa44-1c06-436c-b2d2-716a10769c15'	System	10 Nov 2020 03:21:29
User entered 'Some interference with activity (2)'	System	10 Nov 2020 03:21:29

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(41)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-09T21:21:25', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'ab73fa44-1c06-436c-b2d2-716a10769c15'	System	10 Nov 2020 03:21:29
User entered '09 Nov 2020 21:21'	System	10 Nov 2020 03:21:29

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(41)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Nov 2020 12:00'	System	07 Nov 2020 18:30:37

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(41)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Nov 2020 11:59'	System	07 Nov 2020 18:30:37

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(42)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Nov 2020 18:00:54
User entered 'Day 42'	System	08 Nov 2020 18:00:54

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(42)

Generated On: 26 Nov 2020 11:00:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-11T04:15:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7a8db246-4b75-4ef7-8dc1-fa6008c29c0d'	System	11 Nov 2020 10:15:44
User entered 'Some interference with activity (2)'	System	11 Nov 2020 10:15:44

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(42)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-11T04:15:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '7a8db246-4b75-4ef7-8dc1-fa6008c29c0d' User entered '11 Nov 2020 04:15'	System	11 Nov 2020 10:15:44
	System	11 Nov 2020 10:15:44



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(42)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Nov 2020 12:00'	System	08 Nov 2020 18:00:54

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(42)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020 11:59'	System	08 Nov 2020 18:00:54

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(43)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Nov 2020 03:21:29
User entered 'Day 43'	System	10 Nov 2020 03:21:29

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(43)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-11T17:04:55', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e41b06a1-52fb-40e9-b2dc-2f5cfdcf7e7'	System	11 Nov 2020 23:05:02
User entered 'Some interference with activity (2)'	System	11 Nov 2020 23:05:02

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(43)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-11T17:04:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e41b06a1-52fb-40e9-b2dc-2f5cfdcf7e7'	System	11 Nov 2020 23:05:02
User entered '11 Nov 2020 17:04'	System	11 Nov 2020 23:05:02

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(43)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020 12:00'	System	10 Nov 2020 03:21:29

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(43)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Nov 2020 11:59'	System	10 Nov 2020 03:21:29

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(44)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Nov 2020 10:15:44
User entered 'Day 44'	System	11 Nov 2020 10:15:44



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(44)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-12T14:39:46', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '789ab4cf-1afd-4f8a-8771-09f3c1469354'	System	12 Nov 2020 20:39:53
User entered 'Some interference with activity (2)'	System	12 Nov 2020 20:39:53

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(44)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-12T14:39:50', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '789ab4cf-1afd-4f8a-8771-09f3c1469354'	System	12 Nov 2020 20:39:53
User entered '12 Nov 2020 14:39'	System	12 Nov 2020 20:39:53

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(44)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Nov 2020 12:00'	System	11 Nov 2020 10:15:44

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(44)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Nov 2020 11:59'	System	11 Nov 2020 10:15:44

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(45)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Nov 2020 23:05:02
User entered 'Day 45'	System	11 Nov 2020 23:05:02

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(45)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-13T18:17:21', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f83663b0-98dd-4488-859a-2763496c3612'	System	14 Nov 2020 00:17:29
User entered 'Some interference with activity (2)'	System	14 Nov 2020 00:17:29

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(45)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-13T18:17:24', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'f83663b0-98dd-4488-859a-2763496c3612'	System	14 Nov 2020 00:17:29
User entered '13 Nov 2020 18:17'	System	14 Nov 2020 00:17:29

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(45)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Nov 2020 12:00'	System	11 Nov 2020 23:05:02



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(45)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Nov 2020 11:59'	System	11 Nov 2020 23:05:02

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(46)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Nov 2020 20:39:53
User entered 'Day 46'	System	12 Nov 2020 20:39:53

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(46)

Generated On: 26 Nov 2020 11:00:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-15T04:11:29', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e42b0613-6baf-4175-8097-04fd811bfa8b'	System	15 Nov 2020 10:11:35
User entered 'No interference with activity (1)'	System	15 Nov 2020 10:11:35

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(46)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-15T04:11:34', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e42b0613-6baf-4175-8097-04fd811bfa8b' User entered '15 Nov 2020 04:11'	System	15 Nov 2020 10:11:35
	System	15 Nov 2020 10:11:35

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(46)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Nov 2020 12:00'	System	12 Nov 2020 20:39:53

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(46)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Nov 2020 11:59'	System	12 Nov 2020 20:39:53

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(47)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Nov 2020 00:17:29
User entered 'Day 47'	System	14 Nov 2020 00:17:29

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(47)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-15T15:24:29', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8403c127-6409-4783-ae29-0777b766d778'	System	15 Nov 2020 21:24:36
User entered 'Some interference with activity (2)'	System	15 Nov 2020 21:24:36



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(47)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-15T15:24:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8403c127-6409-4783-ae29-0777b766d778'	System	15 Nov 2020 21:24:36
User entered '15 Nov 2020 15:24'	System	15 Nov 2020 21:24:36

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(47)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Nov 2020 12:00'	System	14 Nov 2020 00:17:29

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(47)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020 11:59'	System	14 Nov 2020 00:17:29

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(48)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Nov 2020 10:11:35
User entered 'Day 48'	System	15 Nov 2020 10:11:35

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(48)

Generated On: 26 Nov 2020 11:00:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-16T13:51:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c28ebc46-cd29-48d8-b491-36de039ae35c'	System	16 Nov 2020 19:51:07
User entered 'Some interference with activity (2)'	System	16 Nov 2020 19:51:07

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(48)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-16T13:51:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c28ebc46-cd29-48d8-b491-36de039ae35c' User entered '16 Nov 2020 13:51'	System	16 Nov 2020 19:51:07

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(48)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020 12:00'	System	15 Nov 2020 10:11:35

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(48)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Nov 2020 11:59'	System	15 Nov 2020 10:11:35



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(49)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Nov 2020 21:24:36
User entered 'Day 49'	System	15 Nov 2020 21:24:36

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(49)

Generated On: 26 Nov 2020 11:00:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-18T00:03:25', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dca0ef93-08cf-4719-a42a-e26eb00763b6'	System	18 Nov 2020 06:03:36
User entered 'Some interference with activity (2)'	System	18 Nov 2020 06:03:36

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(49)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-18T00:03:32', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dca0ef93-08cf-4719-a42a-e26eb00763b6' User entered '18 Nov 2020 00:03'	System	18 Nov 2020 06:03:36
	System	18 Nov 2020 06:03:36

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(49)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Nov 2020 12:00'	System	15 Nov 2020 21:24:36

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(49)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Nov 2020 11:59'	System	15 Nov 2020 21:24:36

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(50)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Nov 2020 19:51:07
User entered 'Day 50'	System	16 Nov 2020 19:51:07

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(50)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-18T12:33:24', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0ec19178-b599-4afe-b338-70e92084a946'	System	18 Nov 2020 18:33:30
User entered 'Some interference with activity (2)'	System	18 Nov 2020 18:33:30

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(50)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-18T12:33:28', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '0ec19178-b599-4afe-b338-70e92084a946' User entered '18 Nov 2020 12:33'	System	18 Nov 2020 18:33:30
	System	18 Nov 2020 18:33:30



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(50)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Nov 2020 12:00'	System	16 Nov 2020 19:51:07

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(50)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020 11:59'	System	16 Nov 2020 19:51:07

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(51)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	18 Nov 2020 06:03:36
User entered 'Day 51'	System	18 Nov 2020 06:03:36

US3342200

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(51)

Generated On: 26 Nov 2020 11:00:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-20T05:59:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8178f9ee-d7de-439e-8df2-09a8e93078cd'	System	20 Nov 2020 11:59:37
User entered 'Some interference with activity (2)'	System	20 Nov 2020 11:59:37

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(51)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-20T05:59:29', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8178f9ee-d7de-439e-8df2-09a8e93078cd' User entered '20 Nov 2020 05:59'	System	20 Nov 2020 11:59:37
	System	20 Nov 2020 11:59:37

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(51)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020 12:00'	System	18 Nov 2020 06:03:36

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(51)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Nov 2020 11:59'	System	18 Nov 2020 06:03:36

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(52)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	18 Nov 2020 18:33:30
User entered 'Day 52'	System	18 Nov 2020 18:33:30



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(52)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-21T04:06:12', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '48ecca37-a4dd-451f-8f07-fe03730a2e9f'	System	21 Nov 2020 10:06:20
User entered 'Some interference with activity (2)'	System	21 Nov 2020 10:06:20

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(52)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-21T04:06:17', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '48ecca37-a4dd-451f-8f07-fe03730a2e9f' User entered '21 Nov 2020 04:06'	System	21 Nov 2020 10:06:20
	System	21 Nov 2020 10:06:20

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(52)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Nov 2020 12:00'	System	18 Nov 2020 18:33:30

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(52)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020 11:59'	System	18 Nov 2020 18:33:30

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(53)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	20 Nov 2020 11:59:37
User entered 'Day 53'	System	20 Nov 2020 11:59:37

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(53)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-22T00:46:38', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '75aeb4d9-08bb-44ba-8cb9-0b70abc36d3d'	System	22 Nov 2020 06:46:43
User entered 'No interference with activity (1)'	System	22 Nov 2020 06:46:43

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(53)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-22T00:46:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '75aeb4d9-08bb-44ba-8cb9-0b70abc36d3d' User entered '22 Nov 2020 00:46'	System	22 Nov 2020 06:46:43

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(53)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020 12:00'	System	20 Nov 2020 11:59:37



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(53)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Nov 2020 11:59'	System	20 Nov 2020 11:59:37

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(54)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	21 Nov 2020 10:06:20
User entered 'Day 54'	System	21 Nov 2020 10:06:20

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(54)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-22T17:30:20', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dfdb2577-090f-4b38-88d7-8d7bbb55080e'	System	22 Nov 2020 23:30:27
User entered 'Some interference with activity (2)'	System	22 Nov 2020 23:30:27

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(54)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-22T17:30:23', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'dfdb2577-090f-4b38-88d7-8d7bbb55080e'	System	22 Nov 2020 23:30:27
User entered '22 Nov 2020 17:30'	System	22 Nov 2020 23:30:27

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(54)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Nov 2020 12:00'	System	21 Nov 2020 10:06:20

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(54)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 11:59'	System	21 Nov 2020 10:06:20

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(55)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	22 Nov 2020 06:46:43
User entered 'Day 55'	System	22 Nov 2020 06:46:43

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(55)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-23T12:02:04', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '77ac41b4-755e-4a26-894c-43c4790ad7c5'	System	23 Nov 2020 18:02:09
User entered 'Some interference with activity (2)'	System	23 Nov 2020 18:02:09



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(55)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-23T12:02:07', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '77ac41b4-755e-4a26-894c-43c4790ad7c5'	System	23 Nov 2020 18:02:09
User entered '23 Nov 2020 12:02'	System	23 Nov 2020 18:02:09

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(55)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 12:00'	System	22 Nov 2020 06:46:43

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(55)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Nov 2020 11:59'	System	22 Nov 2020 06:46:43

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(56)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	22 Nov 2020 23:30:27
User entered 'Day 56'	System	22 Nov 2020 23:30:27

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(56)**

**Generated On: 26 Nov 2020 11:00:19**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-24T13:09:57', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '40df58ff-9d03-44b0-aa9b-39286ee6df62'	System	24 Nov 2020 19:10:04
User entered 'Some interference with activity (2)'	System	24 Nov 2020 19:10:04

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(56)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-24T13:09:59', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '40df58ff-9d03-44b0-aa9b-39286ee6df62'	System	24 Nov 2020 19:10:04
User entered '24 Nov 2020 13:09'	System	24 Nov 2020 19:10:04

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(56)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Nov 2020 12:00'	System	22 Nov 2020 23:30:27

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(56)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Nov 2020 11:59'	System	22 Nov 2020 23:30:27



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(57)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Nov 2020 18:02:09
User entered 'Day 57'	System	23 Nov 2020 18:02:09

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(57)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Nov 2020 12:00'	System	23 Nov 2020 18:02:09

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(57)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Nov 2020 11:59'	System	23 Nov 2020 18:02:09

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(58)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	24 Nov 2020 19:10:04
User entered 'Day 58'	System	24 Nov 2020 19:10:04

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(58)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Nov 2020 12:00'	System	24 Nov 2020 19:10:04

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(58)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Nov 2020 11:59'	System	24 Nov 2020 19:10:04

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 07:37:46
User entered 'Day 8'	System	06 Oct 2020 07:37:46

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T16:49:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'da6dad4-45e4-4da5-985d-579372c606af' User entered 'No (N)'	System	07 Oct 2020 21:49:05



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-07T16:49:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'da6dad4-45e4-4da5-985d-579372c606af' User entered '07 Oct 2020 16:49'	System	07 Oct 2020 21:49:05
	System	07 Oct 2020 21:49:05

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 07:37:46

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 07:37:46

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 09:30:27
User entered 'Day 9'	System	07 Oct 2020 09:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-08T12:00:39', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3f706fe5-5ba8-467d-b383-8d645024f97d' User entered 'No (N)'	System	08 Oct 2020 17:01:08
	System	08 Oct 2020 17:01:08

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-08T12:00:42', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3f706fe5-5ba8-467d-b383-8d645024f97d' User entered '08 Oct 2020 12:00'	System	08 Oct 2020 17:01:08
	System	08 Oct 2020 17:01:08

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 09:30:27

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 09:30:27



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 21:48:31
User entered 'Day 10'	System	07 Oct 2020 21:48:31

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-09T12:15:25', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '75222927-1e4d-423a-ab77-a0fd504d9ef8'	System	09 Oct 2020 17:15:33
User entered 'No (N)'	System	09 Oct 2020 17:15:33

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-09T12:15:29', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '75222927-1e4d-423a-ab77-a0fd504d9ef8' User entered '09 Oct 2020 12:15'	System	09 Oct 2020 17:15:33
	System	09 Oct 2020 17:15:33

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 21:48:31

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 21:48:31

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 17:00:27
User entered 'Day 11'	System	08 Oct 2020 17:00:27

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-10T12:04:30', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3352a37d-fd33-4c2a-a1f5-c5c163bcbdb2' User entered 'No (N)'	System	10 Oct 2020 17:04:36
	System	10 Oct 2020 17:04:36

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-10T12:04:32', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3352a37d-fd33-4c2a-a1f5-c5c163bcbdb2' User entered '10 Oct 2020 12:04'	System	10 Oct 2020 17:04:36
	System	10 Oct 2020 17:04:36



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 17:00:27

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 17:00:27

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 17:14:47
User entered 'Day 12'	System	09 Oct 2020 17:14:47

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(12)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-11T17:27:04', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9a8e1bf8-1b7d-4337-bf40-85ba360d6e02'	System	11 Oct 2020 22:27:08
User entered 'No (N)'	System	11 Oct 2020 22:27:08

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-11T17:27:06', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9a8e1bf8-1b7d-4337-bf40-85ba360d6e02' User entered '11 Oct 2020 17:27'	System	11 Oct 2020 22:27:08
	System	11 Oct 2020 22:27:08

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 17:14:47

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 17:14:47

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(13)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Oct 2020 17:04:11
User entered 'Day 13'	System	10 Oct 2020 17:04:11



US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(13)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-12T16:02:42', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a93271d5-26c7-4043-9b47-e7af0390035d'	System	12 Oct 2020 21:02:52
User entered 'Yes (Y)'	System	12 Oct 2020 21:02:52

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(13)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-12T16:02:48', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a93271d5-26c7-4043-9b47-e7af0390035d' User entered '12 Oct 2020 16:02'	System	12 Oct 2020 21:02:52
	System	12 Oct 2020 21:02:52

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(13)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	10 Oct 2020 17:04:11

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(13)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	10 Oct 2020 17:04:11

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(14)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Oct 2020 22:26:46
User entered 'Day 14'	System	11 Oct 2020 22:26:46

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(14)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T06:26:52', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'bc665186-0351-4c0a-8c54-e2a967815cb7'	System	14 Oct 2020 11:26:58
User entered 'No (N)'	System	14 Oct 2020 11:26:58

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(14)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T06:26:56', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'bc665186-0351-4c0a-8c54-e2a967815cb7' User entered '14 Oct 2020 06:26'	System	14 Oct 2020 11:26:58
	System	14 Oct 2020 11:26:58

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(14)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	11 Oct 2020 22:26:46



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(14)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	11 Oct 2020 22:26:46

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(15)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 21:02:18
User entered 'Day 15'	System	12 Oct 2020 21:02:18

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(15)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T13:41:09', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '88236280-c53c-4fc7-b11e-ac1b71be33b5'	System	14 Oct 2020 18:41:36
User entered 'No (N)'	System	14 Oct 2020 18:41:36

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(15)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-14T13:41:29', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '88236280-c53c-4fc7-b11e-ac1b71be33b5'	System	14 Oct 2020 18:41:36
User entered '14 Oct 2020 13:41'	System	14 Oct 2020 18:41:36

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(15)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 21:02:18

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(15)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 21:02:18

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(16)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 11:26:26
User entered 'Day 16'	System	14 Oct 2020 11:26:26

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(16)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T02:17:14', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '60aba033-6c86-49c5-9164-59d75598c608'	System	16 Oct 2020 07:17:22
User entered 'No (N)'	System	16 Oct 2020 07:17:22



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(16)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T02:17:19', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '60aba033-6c86-49c5-9164-59d75598c608' User entered '16 Oct 2020 02:17'	System	16 Oct 2020 07:17:22
	System	16 Oct 2020 07:17:22

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(16)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 11:26:26

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(16)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 11:26:26

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(17)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 18:40:52
User entered 'Day 17'	System	14 Oct 2020 18:40:52

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(17)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T12:08:47', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'badf3f43-a9e4-459f-a44e-5bf987330931'	System	16 Oct 2020 17:08:52
User entered 'No (N)'	System	16 Oct 2020 17:08:52

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(17)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-16T12:08:50', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'badf3f43-a9e4-459f-a44e-5bf987330931' User entered '16 Oct 2020 12:08'	System	16 Oct 2020 17:08:52
	System	16 Oct 2020 17:08:52

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(17)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 18:40:52

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(17)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 18:40:52



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(18)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Oct 2020 17:08:49
DataPoint Inactivated.	System	16 Oct 2020 17:08:42
Data entry locked.	System	16 Oct 2020 07:16:52
User entered 'Day 18'	System	16 Oct 2020 07:16:52

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(18)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-17T15:00:19', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '801347a2-8845-4bf0-a75e-bc277b5bf663'	System	17 Oct 2020 20:00:27
User entered 'No (N)'	System	17 Oct 2020 20:00:27
DataPoint Activated.	System	16 Oct 2020 17:08:49
DataPoint Inactivated.	System	16 Oct 2020 17:08:42

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(18)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-17T15:00:23', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '801347a2-8845-4bf0-a75e-bc277b5bf663'	System	17 Oct 2020 20:00:27
User entered '17 Oct 2020 15:00'	System	17 Oct 2020 20:00:27
DataPoint Activated.	System	16 Oct 2020 17:08:49
DataPoint Inactivated.	System	16 Oct 2020 17:08:42

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(18)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Oct 2020 17:08:49
DataPoint Inactivated.	System	16 Oct 2020 17:08:42
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 07:16:52

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(18)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Oct 2020 17:08:49
DataPoint Inactivated.	System	16 Oct 2020 17:08:42
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 07:16:52

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(19)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 17:08:49
User entered 'Day 19'	System	16 Oct 2020 17:08:49

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(19)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-18T12:10:09', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '77c95a9d-94e8-4d0b-9e20-2605f4c87bba' User entered 'No (N)'	System	18 Oct 2020 17:10:20

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(19)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-18T12:10:12', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '77c95a9d-94e8-4d0b-9e20-2605f4c87bba' User entered '18 Oct 2020 12:10'	System	18 Oct 2020 17:10:20
	System	18 Oct 2020 17:10:20



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(19)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 17:08:49

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(19)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 17:08:49

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(20)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Oct 2020 20:00:18
User entered 'Day 20'	System	17 Oct 2020 20:00:18

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(20)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-19T16:38:55', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3164eb21-c5e1-44a5-8d90-1994d29a8db7'	System	19 Oct 2020 21:39:01
User entered 'No (N)'	System	19 Oct 2020 21:39:01

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(20)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-19T16:38:57', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3164eb21-c5e1-44a5-8d90-1994d29a8db7' User entered '19 Oct 2020 16:38'	System	19 Oct 2020 21:39:01

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(20)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	17 Oct 2020 20:00:18

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(20)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	17 Oct 2020 20:00:18

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(21)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	18 Oct 2020 17:10:07
User entered 'Day 21'	System	18 Oct 2020 17:10:07



US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(21)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-20T12:39:18', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3186c849-261a-4d9c-83ba-c89fd6c1f974'	System	20 Oct 2020 17:39:24
User entered 'No (N)'	System	20 Oct 2020 17:39:24

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(21)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-20T12:39:21', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3186c849-261a-4d9c-83ba-c89fd6c1f974' User entered '20 Oct 2020 12:39'	System	20 Oct 2020 17:39:24
	System	20 Oct 2020 17:39:24

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(21)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	18 Oct 2020 17:10:07

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(21)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	18 Oct 2020 17:10:07

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(22)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	19 Oct 2020 21:38:54
User entered 'Day 22'	System	19 Oct 2020 21:38:54

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(22)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-21T12:04:37', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3d10fcf5-5f8f-466d-be3b-ea82fd03f8'	System	21 Oct 2020 17:04:42
User entered 'No (N)'	System	21 Oct 2020 17:04:42

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(22)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-21T12:04:40', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3d10fcf5-5f8f-466d-be3b-ea82fd03f8'	System	21 Oct 2020 17:04:42
User entered '21 Oct 2020 12:04'	System	21 Oct 2020 17:04:42

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(22)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 21:38:54



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(22)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 21:38:54

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(23)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 17:39:17
User entered 'Day 23'	System	20 Oct 2020 17:39:17

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(23)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-22T12:08:31', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3274a2c1-a903-43b1-a0f5-16f18579d8da' User entered 'No (N)'	System	22 Oct 2020 17:08:38
	System	22 Oct 2020 17:08:38

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(23)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-22T12:08:34', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3274a2c1-a903-43b1-a0f5-16f18579d8da' User entered '22 Oct 2020 12:08'	System	22 Oct 2020 17:08:38
	System	22 Oct 2020 17:08:38

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(23)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 17:39:17

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(23)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 17:39:17

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(24)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 17:04:40
User entered 'Day 24'	System	21 Oct 2020 17:04:40

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(24)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-23T12:00:29', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '00ba9176-bf63-4ede-83dc-523d8982ddf3'	System	23 Oct 2020 17:00:46
User entered 'No (N)'	System	23 Oct 2020 17:00:46



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(24)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-23T12:00:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '00ba9176-bf63-4ede-83dc-523d8982ddf3' User entered '23 Oct 2020 12:00'	System	23 Oct 2020 17:00:46
	System	23 Oct 2020 17:00:46

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(24)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 17:04:40

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(24)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 17:04:40

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(25)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 17:08:26
User entered 'Day 25'	System	22 Oct 2020 17:08:26

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(25)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-24T18:10:37', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8bb575f3-c3ab-4f19-bccd-4f6b906bc0ed' User entered 'No (N)'	System	24 Oct 2020 23:10:45
	System	24 Oct 2020 23:10:45

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(25)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-24T18:10:42', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8bb575f3-c3ab-4f19-bccd-4f6b906bc0ed' User entered '24 Oct 2020 18:10'	System	24 Oct 2020 23:10:45
	System	24 Oct 2020 23:10:45

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(25)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 17:08:26

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(25)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 17:08:26



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(26)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Oct 2020 17:00:29
User entered 'Day 26'	System	23 Oct 2020 17:00:29

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(26)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-25T13:14:57', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '34caff0f-d529-4b93-8d2c-2f41d072be4f' User entered 'No (N)'	System	25 Oct 2020 18:15:09

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(26)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-25T13:15:07', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '34caff0f-d529-4b93-8d2c-2f41d072be4f' User entered '25 Oct 2020 13:15'	System	25 Oct 2020 18:15:09

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(26)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 17:00:29

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(26)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 17:00:29

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(27)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	24 Oct 2020 22:55:23
User entered 'Day 27'	System	24 Oct 2020 22:55:23

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(27)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-26T12:00:46', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '005541c2-3bfa-4ba1-9a23-e1372bfaa56e'	System	26 Oct 2020 17:01:29
User entered 'No (N)'	System	26 Oct 2020 17:01:29

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(27)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-26T12:00:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '005541c2-3bfa-4ba1-9a23-e1372bfaa56e' User entered '26 Oct 2020 12:00'	System	26 Oct 2020 17:01:29
	System	26 Oct 2020 17:01:29



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(27)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 12:00'	System	24 Oct 2020 22:55:23

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(27)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 11:59'	System	24 Oct 2020 22:55:23

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(28)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	25 Oct 2020 18:14:52
User entered 'Day 28'	System	25 Oct 2020 18:14:52

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(28)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-27T12:15:55', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '75bc9bfb-1af9-4d2f-b091-3aa6b0447778'	System	27 Oct 2020 17:16:01
User entered 'No (N)'	System	27 Oct 2020 17:16:01

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(28)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-27T12:15:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '75bc9bfb-1af9-4d2f-b091-3aa6b0447778' User entered '27 Oct 2020 12:15'	System	27 Oct 2020 17:16:01
	System	27 Oct 2020 17:16:01

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(28)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 12:00'	System	25 Oct 2020 18:14:52

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(28)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 11:59'	System	25 Oct 2020 18:14:52

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(29)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	26 Oct 2020 17:01:15
User entered 'Day 29'	System	26 Oct 2020 17:01:15



US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(29)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-28T13:15:09', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'eca6ad73-bebf-4633-aa9f-b8c1a847fc61'	System	28 Oct 2020 18:15:15
User entered 'No (N)'	System	28 Oct 2020 18:15:15

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(29)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-28T13:15:13', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'eca6ad73-bebf-4633-aa9f-b8c1a847fc61' User entered '28 Oct 2020 13:15'	System	28 Oct 2020 18:15:15

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(29)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 12:00'	System	26 Oct 2020 17:01:15

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(29)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020 11:59'	System	26 Oct 2020 17:01:15

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(30)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	27 Oct 2020 17:15:53
User entered 'Day 30'	System	27 Oct 2020 17:15:53

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(30)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-29T13:11:49', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '991495b1-8e47-4d31-ae54-2905fca5cdcb' User entered 'No (N)'	System	29 Oct 2020 18:11:58
	System	29 Oct 2020 18:11:58

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(30)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-29T13:11:54', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '991495b1-8e47-4d31-ae54-2905fca5cdcb' User entered '29 Oct 2020 13:11'	System	29 Oct 2020 18:11:58
	System	29 Oct 2020 18:11:58

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(30)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 17:15:53



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(30)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 17:15:53

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(31)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Oct 2020 18:15:07
User entered 'Day 31'	System	28 Oct 2020 18:15:07

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(31)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-30T12:00:46', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '66325d47-a1c4-40d2-8051-2f41f7ac6240' User entered 'No (N)'	System	30 Oct 2020 17:01:40
	System	30 Oct 2020 17:01:40

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(31)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-30T12:00:50', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '66325d47-a1c4-40d2-8051-2f41f7ac6240' User entered '30 Oct 2020 12:00'	System	30 Oct 2020 17:01:40
	System	30 Oct 2020 17:01:40

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(31)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 18:15:07

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(31)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 18:15:07

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(32)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	29 Oct 2020 18:11:47
User entered 'Day 32'	System	29 Oct 2020 18:11:47

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(32)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-31T16:57:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e3319374-cdd5-40d9-81ee-f081e67298fc' User entered 'No (N)'	System	31 Oct 2020 21:57:08
	System	31 Oct 2020 21:57:08



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(32)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-10-31T16:57:06', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e3319374-cdd5-40d9-81ee-f081e67298fc' User entered '31 Oct 2020 16:57'	System	31 Oct 2020 21:57:08
	System	31 Oct 2020 21:57:08

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(32)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Oct 2020 12:00'	System	29 Oct 2020 18:11:47

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(32)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Nov 2020 11:59'	System	29 Oct 2020 18:11:47

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(33)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Oct 2020 17:01:16
User entered 'Day 33'	System	30 Oct 2020 17:01:16

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(33)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-01T14:20:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd1752878-a351-49c3-a5ff-065485f58db7'	System	01 Nov 2020 20:20:24
User entered 'No (N)'	System	01 Nov 2020 20:20:24

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(33)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-01T14:20:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd1752878-a351-49c3-a5ff-065485f58db7'	System	01 Nov 2020 20:20:24
User entered '01 Nov 2020 14:20'	System	01 Nov 2020 20:20:24

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(33)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 17:01:16

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(33)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 17:01:16



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(34)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Oct 2020 21:56:59
User entered 'Day 34'	System	31 Oct 2020 21:56:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(34)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-02T17:32:07', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e4a4a2cb-613b-4ef3-980b-514d2029cc25'	System	02 Nov 2020 23:32:17
User entered 'No (N)'	System	02 Nov 2020 23:32:17

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(34)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-02T17:32:13', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e4a4a2cb-613b-4ef3-980b-514d2029cc25'	System	02 Nov 2020 23:32:17
User entered '02 Nov 2020 17:32'	System	02 Nov 2020 23:32:17

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(34)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Nov 2020 12:00'	System	31 Oct 2020 21:56:59

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(34)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Nov 2020 11:59'	System	31 Oct 2020 21:56:59

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(35)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Nov 2020 20:03:38
User entered 'Day 35'	System	01 Nov 2020 20:03:38

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(35)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-03T18:02:03', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8b6d4c1e-765b-409e-becc-b066971b910b'	System	04 Nov 2020 00:02:12
User entered 'Yes (Y)'	System	04 Nov 2020 00:02:12

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(35)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-03T18:02:10', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '8b6d4c1e-765b-409e-becc-b066971b910b' User entered '03 Nov 2020 18:02'	System	04 Nov 2020 00:02:12



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(35)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Nov 2020 12:00'	System	01 Nov 2020 20:03:38

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(35)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Nov 2020 11:59'	System	01 Nov 2020 20:03:38

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(36)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Nov 2020 23:31:59
User entered 'Day 36'	System	02 Nov 2020 23:31:59

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(36)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-05T06:41:45', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '19529384-8580-432b-bce7-932c5226bb6f'	System	05 Nov 2020 12:41:56
User entered 'Yes (Y)'	System	05 Nov 2020 12:41:56

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(36)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-05T06:41:53', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '19529384-8580-432b-bce7-932c5226bb6f' User entered '05 Nov 2020 06:41'	System	05 Nov 2020 12:41:56
	System	05 Nov 2020 12:41:56

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(36)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Nov 2020 12:00'	System	02 Nov 2020 23:31:59

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(36)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Nov 2020 11:59'	System	02 Nov 2020 23:31:59

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(37)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Nov 2020 00:02:03
User entered 'Day 37'	System	04 Nov 2020 00:02:03



US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(37)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-05T12:13:37', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '6669907d-3e63-4656-96a7-2a49b6ba6bf4'	System	05 Nov 2020 18:13:42
User entered 'No (N)'	System	05 Nov 2020 18:13:42

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(37)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-05T12:13:39', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '6669907d-3e63-4656-96a7-2a49b6ba6bf4' User entered '05 Nov 2020 12:13'	System	05 Nov 2020 18:13:42
	System	05 Nov 2020 18:13:42

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(37)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Nov 2020 12:00'	System	04 Nov 2020 00:02:03

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(37)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Nov 2020 11:59'	System	04 Nov 2020 00:02:03

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(38)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Nov 2020 12:41:37
User entered 'Day 38'	System	05 Nov 2020 12:41:37

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(38)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-07T04:41:56', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '97267a9c-9211-42a9-9e80-3753eff45398'	System	07 Nov 2020 10:42:05
User entered 'Yes (Y)'	System	07 Nov 2020 10:42:05

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(38)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-07T04:42:02', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '97267a9c-9211-42a9-9e80-3753eff45398' User entered '07 Nov 2020 04:42'	System	07 Nov 2020 10:42:05
	System	07 Nov 2020 10:42:05

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(38)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Nov 2020 12:00'	System	05 Nov 2020 12:41:37



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(38)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Nov 2020 11:59'	System	05 Nov 2020 12:41:37

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(39)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Nov 2020 18:13:36
User entered 'Day 39'	System	05 Nov 2020 18:13:36

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(39)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-07T12:30:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '5292d9e3-27f8-4b96-b091-ce10985a1cd9' User entered 'No (N)'	System	07 Nov 2020 18:30:44

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(39)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-07T12:30:39', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '5292d9e3-27f8-4b96-b091-ce10985a1cd9' User entered '07 Nov 2020 12:30'	System	07 Nov 2020 18:30:44
	System	07 Nov 2020 18:30:44

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(39)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Nov 2020 12:00'	System	05 Nov 2020 18:13:36

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(39)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Nov 2020 11:59'	System	05 Nov 2020 18:13:36

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(40)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Nov 2020 10:41:41
User entered 'Day 40'	System	07 Nov 2020 10:41:41

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(40)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-08T12:00:57', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '23412317-6d48-487d-aed6-4263a3a9c59c'	System	08 Nov 2020 18:01:07
User entered 'No (N)'	System	08 Nov 2020 18:01:07



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(40)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-08T12:01:00', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '23412317-6d48-487d-aed6-4263a3a9c59c'	System	08 Nov 2020 18:01:07
User entered '08 Nov 2020 12:01'	System	08 Nov 2020 18:01:07

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(40)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Nov 2020 12:00'	System	07 Nov 2020 10:41:41

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(40)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Nov 2020 11:59'	System	07 Nov 2020 10:41:41

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(41)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Nov 2020 18:30:37
User entered 'Day 41'	System	07 Nov 2020 18:30:37

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(41)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-09T21:21:30', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1bde2b73-d9e3-42a0-9d2a-cfa6a31c4954'	System	10 Nov 2020 03:21:46
User entered 'Yes (Y)'	System	10 Nov 2020 03:21:46

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(41)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-09T21:21:38', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '1bde2b73-d9e3-42a0-9d2a-cfa6a31c4954'	System	10 Nov 2020 03:21:46
User entered '09 Nov 2020 21:21'	System	10 Nov 2020 03:21:46

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(41)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Nov 2020 12:00'	System	07 Nov 2020 18:30:37

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(41)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Nov 2020 11:59'	System	07 Nov 2020 18:30:37



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(42)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Nov 2020 18:00:54
User entered 'Day 42'	System	08 Nov 2020 18:00:54

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(42)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-11T04:16:05', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fbe01394-905f-4d50-a3d2-9afd420a136a'	System	11 Nov 2020 10:16:16
User entered 'No (N)'	System	11 Nov 2020 10:16:16

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(42)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-11T04:16:12', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'fbe01394-905f-4d50-a3d2-9afd420a136a' User entered '11 Nov 2020 04:16'	System	11 Nov 2020 10:16:16
	System	11 Nov 2020 10:16:16

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(42)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Nov 2020 12:00'	System	08 Nov 2020 18:00:54

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(42)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020 11:59'	System	08 Nov 2020 18:00:54

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(43)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Nov 2020 03:21:29
User entered 'Day 43'	System	10 Nov 2020 03:21:29

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(43)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-11T17:05:02', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '47bb3757-02e1-43d1-8623-ea0d96fa5d0c'	System	11 Nov 2020 23:05:08
User entered 'No (N)'	System	11 Nov 2020 23:05:08

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(43)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-11T17:05:05', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '47bb3757-02e1-43d1-8623-ea0d96fa5d0c' User entered '11 Nov 2020 17:05'	System	11 Nov 2020 23:05:08
	System	11 Nov 2020 23:05:08



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(43)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020 12:00'	System	10 Nov 2020 03:21:29

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(43)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Nov 2020 11:59'	System	10 Nov 2020 03:21:29

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(44)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Nov 2020 10:15:44
User entered 'Day 44'	System	11 Nov 2020 10:15:44

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(44)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-12T14:39:55', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a40d47e4-d58a-45e9-a20c-02cc650b3a5d'	System	12 Nov 2020 20:40:04
User entered 'No (N)'	System	12 Nov 2020 20:40:04

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(44)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-12T14:39:59', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a40d47e4-d58a-45e9-a20c-02cc650b3a5d' User entered '12 Nov 2020 14:39'	System	12 Nov 2020 20:40:04
	System	12 Nov 2020 20:40:04

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(44)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Nov 2020 12:00'	System	11 Nov 2020 10:15:44

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(44)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Nov 2020 11:59'	System	11 Nov 2020 10:15:44

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(45)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Nov 2020 23:05:02
User entered 'Day 45'	System	11 Nov 2020 23:05:02



US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(45)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-13T18:17:28', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c960046b-9811-481f-a142-b6b2d68f5c13'	System	14 Nov 2020 00:17:55
User entered 'No (N)'	System	14 Nov 2020 00:17:55

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(45)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-13T18:17:53', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c960046b-9811-481f-a142-b6b2d68f5c13'	System	14 Nov 2020 00:17:55
User entered '13 Nov 2020 18:17'	System	14 Nov 2020 00:17:55

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(45)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Nov 2020 12:00'	System	11 Nov 2020 23:05:02

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(45)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Nov 2020 11:59'	System	11 Nov 2020 23:05:02

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(46)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	12 Nov 2020 20:39:53
User entered 'Day 46'	System	12 Nov 2020 20:39:53

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(46)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-15T04:11:42', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c41858e8-86b4-4a86-9ce5-ec765f859e0f'	System	15 Nov 2020 10:11:47
User entered 'No (N)'	System	15 Nov 2020 10:11:47

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(46)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-15T04:11:45', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'c41858e8-86b4-4a86-9ce5-ec765f859e0f' User entered '15 Nov 2020 04:11'	System	15 Nov 2020 10:11:47
	System	15 Nov 2020 10:11:47

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(46)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Nov 2020 12:00'	System	12 Nov 2020 20:39:53



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(46)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Nov 2020 11:59'	System	12 Nov 2020 20:39:53

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(47)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Nov 2020 00:17:29
User entered 'Day 47'	System	14 Nov 2020 00:17:29

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(47)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-15T15:24:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '939fed1e-fe13-425b-9699-448d77b0cfbb'	System	15 Nov 2020 21:24:42
User entered 'No (N)'	System	15 Nov 2020 21:24:42

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(47)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-15T15:24:40', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '939fed1e-fe13-425b-9699-448d77b0cfbb' User entered '15 Nov 2020 15:24'	System	15 Nov 2020 21:24:42
	System	15 Nov 2020 21:24:42

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(47)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Nov 2020 12:00'	System	14 Nov 2020 00:17:29

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(47)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020 11:59'	System	14 Nov 2020 00:17:29

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(48)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Nov 2020 10:11:35
User entered 'Day 48'	System	15 Nov 2020 10:11:35

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(48)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-16T13:51:13', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '817b9019-07f1-4efd-9139-eac093a9f13f' User entered 'No (N)'	System	16 Nov 2020 19:51:18
	System	16 Nov 2020 19:51:18



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(48)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-16T13:51:15', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '817b9019-07f1-4efd-9139-eac093a9f13f' User entered '16 Nov 2020 13:51'	System	16 Nov 2020 19:51:18
	System	16 Nov 2020 19:51:18

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(48)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020 12:00'	System	15 Nov 2020 10:11:35

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(48)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Nov 2020 11:59'	System	15 Nov 2020 10:11:35

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(49)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Nov 2020 21:24:36
User entered 'Day 49'	System	15 Nov 2020 21:24:36

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(49)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-18T00:03:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '93a21e81-4336-4cbd-b8ed-1fca0abc61b6'	System	18 Nov 2020 06:04:10
User entered 'No (N)'	System	18 Nov 2020 06:04:10

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(49)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-18T00:04:08', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '93a21e81-4336-4cbd-b8ed-1fca0abc61b6' User entered '18 Nov 2020 00:04'	System	18 Nov 2020 06:04:10
	System	18 Nov 2020 06:04:10

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(49)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Nov 2020 12:00'	System	15 Nov 2020 21:24:36

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(49)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Nov 2020 11:59'	System	15 Nov 2020 21:24:36



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(50)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Nov 2020 19:51:07
User entered 'Day 50'	System	16 Nov 2020 19:51:07

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(50)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-18T12:33:37', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '503afd3a-a247-434f-b14e-158a1a327c55'	System	18 Nov 2020 18:33:48
User entered 'Yes (Y)'	System	18 Nov 2020 18:33:48

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(50)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-18T12:33:43', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '503afd3a-a247-434f-b14e-158a1a327c55'	System	18 Nov 2020 18:33:48
User entered '18 Nov 2020 12:33'	System	18 Nov 2020 18:33:48

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(50)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Nov 2020 12:00'	System	16 Nov 2020 19:51:07

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(50)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020 11:59'	System	16 Nov 2020 19:51:07

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(51)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	18 Nov 2020 06:03:36
User entered 'Day 51'	System	18 Nov 2020 06:03:36

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(51)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-20T05:59:42', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a549c540-4520-4eb5-8a17-136343f4310d'	System	20 Nov 2020 11:59:48
User entered 'No (N)'	System	20 Nov 2020 11:59:48

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(51)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-20T05:59:45', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'a549c540-4520-4eb5-8a17-136343f4310d' User entered '20 Nov 2020 05:59'	System	20 Nov 2020 11:59:48
	System	20 Nov 2020 11:59:48



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(51)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020 12:00'	System	18 Nov 2020 06:03:36

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(51)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Nov 2020 11:59'	System	18 Nov 2020 06:03:36

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(52)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	18 Nov 2020 18:33:30
User entered 'Day 52'	System	18 Nov 2020 18:33:30

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(52)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-21T04:06:24', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '56b4fdb8-1273-41bb-908f-cfa93b67b7ed'	System	21 Nov 2020 10:06:32
User entered 'No (N)'	System	21 Nov 2020 10:06:32

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(52)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-21T04:06:29', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '56b4fdb8-1273-41bb-908f-cfa93b67b7ed' User entered '21 Nov 2020 04:06'	System	21 Nov 2020 10:06:32
	System	21 Nov 2020 10:06:32

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(52)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Nov 2020 12:00'	System	18 Nov 2020 18:33:30

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(52)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020 11:59'	System	18 Nov 2020 18:33:30

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(53)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	20 Nov 2020 11:59:37
User entered 'Day 53'	System	20 Nov 2020 11:59:37



US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(53)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-22T00:46:47', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e62b8e12-8ef5-453e-bd41-cfa6f099b87e'	System	22 Nov 2020 06:46:53
User entered 'No (N)'	System	22 Nov 2020 06:46:53

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(53)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-22T00:46:51', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'e62b8e12-8ef5-453e-bd41-cfa6f099b87e' User entered '22 Nov 2020 00:46'	System	22 Nov 2020 06:46:53
	System	22 Nov 2020 06:46:53

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(53)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020 12:00'	System	20 Nov 2020 11:59:37

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(53)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Nov 2020 11:59'	System	20 Nov 2020 11:59:37

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(54)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	21 Nov 2020 10:06:20
User entered 'Day 54'	System	21 Nov 2020 10:06:20

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(54)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-22T17:30:34', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9d25c0ac-6ffd-4a87-ae0e-88bf598f9a2a'	System	22 Nov 2020 23:30:39
User entered 'No (N)'	System	22 Nov 2020 23:30:39

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(54)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-22T17:30:37', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '9d25c0ac-6ffd-4a87-ae0e-88bf598f9a2a'	System	22 Nov 2020 23:30:39
User entered '22 Nov 2020 17:30'	System	22 Nov 2020 23:30:39

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(54)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Nov 2020 12:00'	System	21 Nov 2020 10:06:20



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(54)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 11:59'	System	21 Nov 2020 10:06:20

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(55)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	22 Nov 2020 06:46:43
User entered 'Day 55'	System	22 Nov 2020 06:46:43

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(55)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-23T12:02:30', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '29923e59-280b-41f4-a483-3bcaf2b8ab05'	System	23 Nov 2020 18:02:38
User entered 'Yes (Y)'	System	23 Nov 2020 18:02:38

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(55)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-23T12:02:34', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '29923e59-280b-41f4-a483-3bcaf2b8ab05' User entered '23 Nov 2020 12:02'	System	23 Nov 2020 18:02:38
	System	23 Nov 2020 18:02:38

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(55)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 12:00'	System	22 Nov 2020 06:46:43

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(55)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Nov 2020 11:59'	System	22 Nov 2020 06:46:43

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(56)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	22 Nov 2020 23:30:27
User entered 'Day 56'	System	22 Nov 2020 23:30:27

US3342200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(56)

Generated On: 26 Nov 2020 11:00:19

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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-24T13:10:56', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3ba5ab69-0561-4bd6-844c-30bb5c79c75d'	System	24 Nov 2020 19:11:01
User entered 'No (N)'	System	24 Nov 2020 19:11:01



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(56)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-24T13:10:58', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '3ba5ab69-0561-4bd6-844c-30bb5c79c75d'	System	24 Nov 2020 19:11:01
User entered '24 Nov 2020 13:10'	System	24 Nov 2020 19:11:01

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(56)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Nov 2020 12:00'	System	22 Nov 2020 23:30:27

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(56)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Nov 2020 11:59'	System	22 Nov 2020 23:30:27

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(57)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Nov 2020 18:02:09
User entered 'Day 57'	System	23 Nov 2020 18:02:09

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(57)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Nov 2020 12:00'	System	23 Nov 2020 18:02:09

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(57)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Nov 2020 11:59'	System	23 Nov 2020 18:02:09

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(58)**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	24 Nov 2020 19:10:04
User entered 'Day 58'	System	24 Nov 2020 19:10:04

**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(58)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Nov 2020 12:00'	System	24 Nov 2020 19:10:04



**US3342200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(58)**

**Generated On: 26 Nov 2020 11:00:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Nov 2020 11:59'	System	24 Nov 2020 19:10:04

US3342200

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:11:41

US3342200

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '7 Oct 2020'	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:11:41

**US3342200**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:00:19**

[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)	07 Oct 2020 19:11:41

**US3342200**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:00:19**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:11:41

US3342200

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:11:45

**US3342200**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:00:19**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Oct 2020 19:11:45

**US3342200**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:00:19**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 19:47:12



US3342200

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 19:47:12

**US3342200**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:00:19**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Oct 2020 19:47:12

**US3342200**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:00:19**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 19:47:12

US3342200

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 19:47:25

**US3342200**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:00:19**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Oct 2020 19:47:25

**US3342200**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:00:19**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 22:08:18

**US3342200**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:00:19**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 22:08:18

**US3342200**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:00:19**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	26 Oct 2020 22:08:18



**US3342200**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:00:19**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:08:18

US3342200

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 22:08:22

**US3342200**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:00:19**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Oct 2020 22:08:22

US3342200

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:00:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 22:08:41

US3342200

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:00:19

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 22:08:41

US3342200

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:00:19

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Oct 2020 22:08:41

**US3342200**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 11:00:19**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	26 Oct 2020 22:08:41

US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 22:09:31



US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 22:09:31

US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:19

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User entered '15:30'	(b) (4), (b) (6)	26 Oct 2020 22:09:31

**US3342200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:00:19**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 15:30'	System	26 Oct 2020 22:09:31

US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.8' F	(b) (4), (b) (6)	26 Oct 2020 22:09:31

US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	26 Oct 2020 22:09:31

US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:09:31

US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '71'	(b) (4), (b) (6)	26 Oct 2020 22:09:31

**US3342200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:00:19**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	26 Oct 2020 22:09:31



US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '14'	(b) (4), (b) (6)	26 Oct 2020 22:09:31

US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	26 Oct 2020 22:09:31

US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '117'	(b) (4), (b) (6)	26 Oct 2020 22:09:31

**US3342200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 11:00:19**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Oct 2020 22:09:31

US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '77'	(b) (4), (b) (6)	26 Oct 2020 22:09:31

US3342200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Oct 2020 22:09:31

US3342200

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:19

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 22:09:42

US3342200

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 22:09:42



US3342200

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	28 Oct 2020 19:40:05

US3342200

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:19

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 26-OCT-2020. However, collection date is missing in GCL. Please confirm if 26-OCT-2020 is correct date to update in GCL records.' answered with 'Visit 3 Day 57 collection date confirmed as 26-OCT-2020.' (Site from DM).	Andrew Bell (b) (4) (b) (4)	12 Nov 2020 15:59:20
User opened query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 26-OCT-2020. However, collection date is missing in GCL. Please confirm if 26-OCT-2020 is correct date to update in GCL records.' (Site from DM).	(b) (4), (b) (6) (b) (4)	10 Nov 2020 10:00:52
User entered '26 Oct 2020'	Tiffany Lemuz (b) (4) (b) (4) (b) (4)	28 Oct 2020 19:40:05

**US3342200**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 11:00:19**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '17:06'	Tiffany Lemuz (b) (4)	28 Oct 2020 19:40:05

**US3342200**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 11:00:19**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 17:06'	System	28 Oct 2020 19:40:05

US3342200

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 22:09:45

**US3342200**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:00:19**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Oct 2020 22:09:45

**US3342200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 64'	System	04 Sep 2020 21:55:03

**US3342200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-04T09:43:12', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '59aa734d-2e59-4249-8202-46633a3278b1'	System	04 Nov 2020 15:43:34
User entered 'No (N)'	System	04 Nov 2020 15:43:34



**US3342200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Have you been exposed to someone with 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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-04T09:43:16', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '59aa734d-2e59-4249-8202-46633a3278b1'	System	04 Nov 2020 15:43:34
User entered 'No (N)'	System	04 Nov 2020 15:43:34

**US3342200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-04T09:43:22', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '59aa734d-2e59-4249-8202-46633a3278b1' User entered '04 Nov 2020 09:43:22'	System	04 Nov 2020 15:43:34
	System	04 Nov 2020 15:43:34

**US3342200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered '04 Nov 2020 00:01'	System	04 Sep 2020 21:55:03

**US3342200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered '08 Nov 2020 23:59'	System	04 Sep 2020 21:55:03

**US3342200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 71'	System	04 Sep 2020 21:55:03

**US3342200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-11T04:16:29', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'aaf2db1b-3936-4384-a2ae-e34fd9787e0c'	System	11 Nov 2020 10:16:52
User entered 'No (N)'	System	11 Nov 2020 10:16:52

**US3342200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Have you been exposed to someone with 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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-11T04:16:36', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'aaf2db1b-3936-4384-a2ae-e34fd9787e0c'	System	11 Nov 2020 10:16:52
User entered 'No (N)'	System	11 Nov 2020 10:16:52

**US3342200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-11T04:16:48', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'aaf2db1b-3936-4384-a2ae-e34fd9787e0c' User entered '11 Nov 2020 04:16:48'	System	11 Nov 2020 10:16:52
	System	11 Nov 2020 10:16:52



**US3342200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered '11 Nov 2020 00:01'	System	04 Sep 2020 21:55:03

**US3342200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered '15 Nov 2020 23:59'	System	04 Sep 2020 21:55:03

**US3342200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered 'Day 78'	System	04 Sep 2020 21:55:03

**US3342200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-18T00:04:21', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd0745912-b708-4f26-bcb8-ef2f184fdacc'	System	18 Nov 2020 06:04:44
User entered 'No (N)'	System	18 Nov 2020 06:04:44

**US3342200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Have you been exposed to someone with 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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-18T00:04:33', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd0745912-b708-4f26-bcb8-ef2f184fdacc'	System	18 Nov 2020 06:04:44
User entered 'No (N)'	System	18 Nov 2020 06:04:44

**US3342200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-18T00:04:41', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: 'd0745912-b708-4f26-bcb8-ef2f184fdacc' User entered '18 Nov 2020 00:04:41'	System	18 Nov 2020 06:04:44
	System	18 Nov 2020 06:04:44

**US3342200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered '18 Nov 2020 00:01'	System	04 Sep 2020 21:55:03

**US3342200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 21:55:03
User entered '22 Nov 2020 23:59'	System	04 Sep 2020 21:55:03



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '01 Nov 2020 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '05 Nov 2020 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '08 Nov 2020 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '12 Nov 2020 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '15 Nov 2020 00:01'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '19 Nov 2020 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-22T00:47:12', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2263e1aa-6deb-4eaf-b19a-688c6ca1830c'	System	22 Nov 2020 06:48:17
User entered 'Yes (Y)'	System	22 Nov 2020 06:48:17

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

Have you been exposed to someone with 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 (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-22T00:47:35', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2263e1aa-6deb-4eaf-b19a-688c6ca1830c'	System	22 Nov 2020 06:48:17
User entered 'No (N)'	System	22 Nov 2020 06:48:17

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-22T00:47:45', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2263e1aa-6deb-4eaf-b19a-688c6ca1830c' User entered 'No (N)'	System	22 Nov 2020 06:48:17

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-22T00:48:07', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2263e1aa-6deb-4eaf-b19a-688c6ca1830c'	System	22 Nov 2020 06:48:17
User entered 'No (N)'	System	22 Nov 2020 06:48:17

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2D2D1647-7C35-4DCA-ADA3-8E1DAA921DDC)', Time: '2020-11-22T00:48:10', User OID: 'PatientReportedOutcome (US3342200)', ODM File OID: '2263e1aa-6deb-4eaf-b19a-688c6ca1830c'	System	22 Nov 2020 06:48:17
User entered '22 Nov 2020 00:48:10'	System	22 Nov 2020 06:48:17

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 05:39:53



**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 05:39:53

**US3342200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 11:00:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:39:53
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 05:39:53

US3342200

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	23 Nov 2020 22:50:24

US3342200

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Stefanie Mott (b) (4)	23 Nov 2020 22:50:24

US3342200

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Stefanie Mott (b) (4)	23 Nov 2020 22:50:24

**US3342200**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 11:00:19**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	23 Nov 2020 22:50:24

US3342200

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	23 Nov 2020 22:50:29



**US3342200**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 11:00:19**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Nov 2020 22:50:29

US3342200

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:00:19

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:28:06

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:19

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review AE and please update to specify the type of Rash (e.g. Maculopapular, Pustular, etc.) and if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:49:39
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis atopic, LLT: Dermatitis atopic aggravated - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 23:01:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 23:01:15
Data point term sent to Coder	System	23 Nov 2020 22:10:24
Query 'Per DM CLR: Please review AE and please update to specify the type of Rash (e.g. Maculopapular, Pustular, etc.) and if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' answered with 'updated term' (Site from DM).	Eileen Euperio (b) (4)	23 Nov 2020 22:10:23
Coding entries removed.	Eileen Euperio (b) (4)	23 Nov 2020 22:10:18
User entered 'atopic dermatitis exacerbation' reason for change: Data Entry Error	Eileen Euperio (b) (4)	23 Nov 2020 22:10:18
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash, LLT: Rash on legs & arms - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 16:14:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 16:14:34
User opened query 'Per DM CLR: Please review AE and please update to specify the type of Rash (e.g. Maculopapular, Pustular, etc.) and if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:39:56
User closed query 'Per MM: Specify location of rash' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 16:47:06

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:19

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per MM: Specify location of rash' answered with 'Location specified in description and narrative.' (Site from DM).	Andrew Bell (b) (4)	06 Nov 2020 17:01:02
Data point term sent to Coder	(b) (4)	
Coding entries removed.	System	06 Nov 2020 17:00:44
	Andrew Bell (b) (4)	06 Nov 2020 17:00:39
	(b) (4)	
User entered 'RASH (BOTH ARMS AND LEGS)' reason for change: Data Entry Error	Andrew Bell (b) (4)	06 Nov 2020 17:00:39
User opened query 'Per MM: Specify location of rash' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 16:53:08
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash, LLT: Rash - version MedDRA\23.0.	Coder Import (b) (4)	05 Oct 2020 19:33:20
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Oct 2020 19:33:20
	(b) (4)	
Data point term sent to Coder	System	05 Oct 2020 19:32:42
User entered 'RASH'	Morgan Schulle (b) (4)	05 Oct 2020 19:32:19
	(b) (4)	

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:19

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19



**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 11:00:19**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '22:00'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 11:00:19**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 22:00'	System	05 Oct 2020 19:32:19

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 11:00:19**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:19

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:19

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 11:00:19**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 19:32:19

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 11:00:19**

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19



**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 11:00:19**

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 11:00:19**

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 11:00:19**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:19

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 11:00:19**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19



US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 11:00:19**

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:19

[None](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Per SAE narrative, "using Triamcinolone as needed". If this medication was also given for this AE, please include this AE as one of the CM's indication, so there will be an appropriate match. Otherwise, please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:49:53
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Per SAE narrative, "using Triamcinolone as needed". If this medication was also given for this AE, please include this AE as one of the CM's indication, so there will be an appropriate match. Otherwise, please review and add a Con Medication as appropriate or update action taken.' answered with 'triamcinolone added to con med for this AE' (Site from DM).	Stefanie Mott (b) (4)	23 Nov 2020 22:16:05
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Per SAE narrative, "using Triamcinolone as needed". If this medication was also given for this AE, please include this AE as one of the CM's indication, so there will be an appropriate match. Otherwise, please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:40:19
User entered 'I'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19



**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 11:00:19**

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 11:00:19**

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 11:00:19**

[Narrative](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Stefanie Mott (b) (4) [REDACTED]	23 Nov 2020 22:16:10
User entered 'RASH - BILATERAL ARMS AND LEGS. USING Triamcinolone AS NEEDED.'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:32:19

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 11:00:19**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Oct 2020 19:32:19

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 11:00:19**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Oct 2020 19:32:19

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:00:19

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 22:08:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 22:08:27
Data point term sent to Coder	System	26 Oct 2020 22:07:11
User entered 'Myalgia'	(b) (4), (b) (6) (b) (4)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:00:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 11:00:19**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 22:06:14



US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:00:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:00:19

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '5 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:00:19

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:06:14

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 11:00:19**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 22:06:14

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 11:00:19**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:00:19

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 11:00:19**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:06:14

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 11:00:19**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 22:06:14



**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 11:00:19**

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:00:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 11:00:19**

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 11:00:19**

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 11:00:19**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:00:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:00:19

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:06:14

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 11:00:19**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:06:14



US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:00:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:06:14

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 11:00:19**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 11:00:19**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:00:19

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:00:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:00:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:00:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 11:00:19**

[None](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	26 Oct 2020 22:06:14



US3342200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:00:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 11:00:19**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 11:00:19**

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	26 Oct 2020 22:06:14

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 11:00:19**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:06:14

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 11:00:19**

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:06:14

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 11:00:19**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Oct 2020 22:06:14

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 11:00:19**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Oct 2020 22:06:14

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:00:19

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 22:08:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 22:08:28
Data point term sent to Coder	System	26 Oct 2020 22:08:12
User entered 'Fatigue'	(b) (4), (b) (6)	26 Oct 2020 22:07:42



US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:00:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:00:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:00:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:00:19

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '4 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:00:19**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:07:42

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:00:19**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 22:07:42

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:00:19**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:00:19

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 22:07:42



**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:00:19**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:07:42

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:00:19**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 22:07:42

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:00:19**

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:00:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:00:19**

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:00:19**

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:00:19**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:00:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:07:42



US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:00:19

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:07:42

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:00:19**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:00:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:00:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:00:19**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:00:19**

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

US3342200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:00:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:00:19**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Oct 2020 22:07:42



**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:00:19**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:00:19**

[None](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:00:19**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:00:19**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:00:19**

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	26 Oct 2020 22:07:42

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:00:19**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:07:42

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:00:19**

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 22:07:42

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:00:19**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Oct 2020 22:07:42



**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 11:00:19**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Oct 2020 22:07:42

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 11:00:19**

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:02
User entered 'USA-US203-2020-mRNA-1273-P301000006'	System	24 Nov 2020 20:39:57
User entered 'New'	(b) (4), (b) (6)	24 Nov 2020 20:39:57

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Intraductal proliferative breast lesion, LLT: Carcinoma in situ of breast ductal - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 22:50:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 22:50:14
Data point term sent to Coder	System	23 Nov 2020 22:49:21
User entered 'DUCTAL CARCINOMA IN SITU RIGHT BREAST'	Stefanie Mott (b) (4) (b) (4) (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '20 Nov 2020'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26



**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 11:00:19**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 11:00:19**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26



US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 11:00:19**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26



US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

[Other medically important event](#)

Audit	User	Time (GMT)
User entered 'I'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

[None](#)

Audit	User	Time (GMT)
User entered '1'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	23 Nov 2020 22:48:26



US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

US3342200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:00:19

[Narrative](#)

Audit	User	Time (GMT)
User entered 'patient had an abnormal mammogram Aug2020 right breast and had a right breast biopsy. results from Aug2020 biopsy were benign. Patient had annual exam Oct2020 and was told by provider to have another mammogram and u/s of right breast due to another right breast lump. Patient had mammogram and u/s Oct2020 and then had a biopsy of right breast 18Nov2020. Patient was diagnosed with ductal carcinoma in situ of the right breast following biopsy on 20Nov2020. Patient will be seeing breast cancer specialist and has not started medication or radiation at this time.'	Stefanie Mott (b) (4)	23 Nov 2020 22:48:26

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 11:00:19**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Nov 2020 22:48:26

**US3342200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 11:00:19**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Nov 2020 22:48:26

US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 26 Nov 2020 11:00:19**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Sep 2020 22:02:19

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:19

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 22:04:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 22:04:46
Data point term sent to Coder	System	04 Sep 2020 22:03:52
User entered 'Vitamin D'	Stefanie Mott (b) (4)	04 Sep 2020 22:03:36

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 22:03:36

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:19

[Indication](#)

Audit	User	Time (GMT)
User entered 'Vitamin D deficiency'	Stefanie Mott (b) (4)	04 Sep 2020 22:03:36



US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:00:19**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5000'	Stefanie Mott (b) (4)	04 Sep 2020 22:03:36

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:19

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Stefanie Mott (b) (4)	04 Sep 2020 22:03:36

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 22:03:36

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:19

[Frequency](#)

Audit	User	Time (GMT)
User entered 'every week (QS)'	Stefanie Mott (b) (4)	04 Sep 2020 22:03:36

US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:00:19**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 22:03:36

US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:00:19**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Stefanie Mott (b) (4)	04 Sep 2020 22:03:36

US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:00:19**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 22:03:36

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Stefanie Mott (b) (4)	04 Sep 2020 22:03:36



US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:19

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 22:03:36

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:19

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Sep 2020 22:03:36

US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:00:19**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 22:03:36

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 22:03:36

**US3342200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:00:19**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 22:03:36

**US3342200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:00:19**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 22:03:36

**US3342200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 11:00:19**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	04 Sep 2020 22:03:36

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:19

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 22:05:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 22:05:47
Data point term sent to Coder	System	04 Sep 2020 22:04:52
User entered 'Singulair'	Stefanie Mott (b) (4)	04 Sep 2020 22:04:24



US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 22:04:24

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:19

[Indication](#)

Audit	User	Time (GMT)
User entered 'Seasonal allergies'	Stefanie Mott (b) (4)	04 Sep 2020 22:04:24

US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:00:19**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Stefanie Mott (b) (4)	04 Sep 2020 22:04:24

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:19

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Stefanie Mott (b) (4)	04 Sep 2020 22:04:24

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 22:04:24

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:19

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Stefanie Mott (b) (4)	04 Sep 2020 22:04:24

US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:00:19**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 22:04:24

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:19

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Stefanie Mott (b) (4)	04 Sep 2020 22:04:24



US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:00:19**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 22:04:24

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Stefanie Mott (b) (4)	04 Sep 2020 22:04:24

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:19

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 22:04:24

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:19

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Sep 2020 22:04:24

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 22:04:24

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 22:04:24

**US3342200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:00:19**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 22:04:24

**US3342200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:00:19**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 22:04:24



**US3342200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 11:00:19**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 22:04:24

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:19

[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)	05 Sep 2020 05:39:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 05:39:44
Data point term sent to Coder	System	04 Sep 2020 22:05:54
User entered 'Flu vaccine'	Stefanie Mott (b) (4) (b) (4) (b) (4)	04 Sep 2020 22:05:41

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 22:05:41

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:19

[Indication](#)

Audit	User	Time (GMT)
User entered 'influenza prevention'	Stefanie Mott (b) (4)	04 Sep 2020 22:05:41

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:19

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Stefanie Mott (b) (4)	04 Sep 2020 22:05:41

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:19

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Stefanie Mott (b) (4)	04 Sep 2020 22:05:41

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User closed query 'Per CDM: If dose unit is Other, specify is recorded as ' DOSE' which is unclear.Please consider to verify and update data appropriately else clarify.Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 06:25:00
Query 'Per CDM: If dose unit is Other, specify is recorded as ' DOSE' which is unclear.Please consider to verify and update data appropriately else clarify.Thank you. ' answered with 'Updated from "dose" to "injection" due to unknown exact dosage.' (Site from DM).	Andrew Bell (b) (4) (b) (4)	07 Oct 2020 14:34:07
User entered 'INJECTION' reason for change: Data Entry Error	Andrew Bell (b) (4) (b) (4)	07 Oct 2020 14:33:33
User opened query 'Per CDM: If dose unit is Other, specify is recorded as ' DOSE' which is unclear.Please consider to verify and update data appropriately else clarify.Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 06:24:49
User entered 'Dose'	Stefanie Mott (b) (4)	04 Sep 2020 22:05:41

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:19

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Stefanie Mott (b) (4)	04 Sep 2020 22:05:41



US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:19

If frequency is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 22:05:41

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:19

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	Stefanie Mott (b) (4)	04 Sep 2020 22:05:41

US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:00:19**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	04 Sep 2020 22:05:41

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '05 Aug 2020'	Stefanie Mott (b) (4)	04 Sep 2020 22:05:41

US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:00:19**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	04 Sep 2020 22:05:41

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:19

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Sep 2020 22:05:41

US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:00:19**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '05 Aug 2020'	Stefanie Mott (b) (4)	04 Sep 2020 22:05:41

US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:00:19**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4) [REDACTED] [REDACTED]	04 Sep 2020 22:05:41



**US3342200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:00:19**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 22:05:41

**US3342200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:00:19**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 22:05:41

**US3342200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 11:00:19**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 22:05:41

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:19

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 05:45:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 05:45:29
Data point term sent to Coder	System	05 Oct 2020 19:27:28
User entered 'Triamcinolone 1%'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:26:55

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:26:55

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:19

[Indication](#)

Audit	User	Time (GMT)
User entered 'ATOPIC DERMATITIS'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:26:55

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:19

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:26:55

US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:00:19**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:26:55



US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:00:19**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'APPLICATION'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:26:55

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:19

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:26:55

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:26:55

US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:00:19**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Topical (TOPICAL)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:26:55

US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:00:19**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:26:55

US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:00:19**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2000'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:26:55

US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:00:19**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:26:55

US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:00:19**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:26:55



US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:00:19**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:26:55

US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:00:19**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 19:26:55

**US3342200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:00:19**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 19:26:55

**US3342200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:00:19**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 19:26:55

**US3342200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 11:00:19**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 19:26:55

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:00:19

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN EXTRA STRENGTH - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 20:03:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 20:03:54
Data point term sent to Coder	System	07 Oct 2020 19:15:18
User entered 'Acetaminophen extra strength'	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:14:49

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:00:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:14:49

**US3342200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:00:19**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Headache (solicited reaction - Vaccine #2)'	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:14:49



US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:00:19**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:14:49

US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:00:19**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:14:49

US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:00:19**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:14:49

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:00:19

[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:14:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 19:14:57
User entered 'once (ONCE)' reason for change: Data Entry Error	Ethan Shotton (b) (4)	07 Oct 2020 19:14:57
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	07 Oct 2020 19:14:49
User entered empty.	Ethan Shotton (b) (4)	07 Oct 2020 19:14:49
	(b) (4)	

US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:00:19**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:14:49

US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:00:19**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:14:49

**US3342200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:00:19**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:14:49

US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:00:19**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020'	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:14:49



US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:00:19**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:14:49

**US3342200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:00:19**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:14:49

US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:00:19**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '03 Oct 2020'	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:14:49

US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:00:19**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	07 Oct 2020 19:14:49

**US3342200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:00:19**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:14:49

**US3342200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:00:19**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:14:49

**US3342200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 11:00:19**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:14:49

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:19

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 04:12:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 04:12:05
Data point term sent to Coder	System	23 Nov 2020 22:16:31
User entered 'triamcinolone 0.1%'	Stefanie Mott (b) (4) (b) (4) (b) (4)	23 Nov 2020 22:15:43



US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	23 Nov 2020 22:15:43

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:19

[Indication](#)

Audit	User	Time (GMT)
User entered 'atopic dermatitis exacerbation AE'	Stefanie Mott (b) (4)	23 Nov 2020 22:15:43

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:19

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Stefanie Mott (b) (4)	23 Nov 2020 22:15:43

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:19

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Stefanie Mott (b) (4)	23 Nov 2020 22:15:43

US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:00:19**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'application'	Stefanie Mott (b) (4)	23 Nov 2020 22:15:43

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:19

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Stefanie Mott (b) (4)	23 Nov 2020 22:15:43

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:19

If frequency is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	23 Nov 2020 22:15:43

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:19

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Topical (TOPICAL)'	Stefanie Mott (b) (4)	23 Nov 2020 22:15:43



US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:00:19**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	23 Nov 2020 22:15:43

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '04 Sep 2020'	Stefanie Mott (b) (4)	23 Nov 2020 22:15:43

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:19

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Stefanie Mott (b) (4)	23 Nov 2020 22:15:43

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:19

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	23 Nov 2020 22:15:43

US3342200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:00:19**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Stefanie Mott (b) (4)	23 Nov 2020 22:15:43

US3342200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stefanie Mott (b) (4)	23 Nov 2020 22:15:43

**US3342200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:00:19**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 22:15:43

**US3342200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:00:19**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 22:15:43



**US3342200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 11:00:19**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 22:15:43

US3342200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:00:19

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	23 Nov 2020 23:01:56

US3342200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:00:19

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Nov 2020'	Stefanie Mott (b) (4)	23 Nov 2020 23:02:22

US3342200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:00:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'right breast lump biopsy'	Stefanie Mott (b) (4)	23 Nov 2020 23:02:22

US3342200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:00:19

[Indication](#)

Audit	User	Time (GMT)
User entered 'Diagnostic (DIAGNOSTIC)'	Stefanie Mott (b) (4)	23 Nov 2020 23:02:22

US3342200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:00:19

If indication is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stefanie Mott (b) (4)	23 Nov 2020 23:02:22

**US3342200**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:00:19**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'USA-US203-2020-MRNA-1273-P301000006'	System	24 Nov 2020 20:39:57

**US3342200**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:00:19**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'Yes (Y)'	System	24 Nov 2020 20:39:57



**US3342200**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:00:19**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

**US3342200**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:00:19**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

**US3342200**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:00:19**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

**US3342200**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:00:19**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

**US3342200**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:00:19**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

**US3342200**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:00:19**

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'Yes (Y)'	System	24 Nov 2020 20:39:57

**US3342200**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:00:19**

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	24 Nov 2020 20:40:28

**US3342200**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:00:19**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Nov 2020 20:40:28



**US3342200**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:00:19**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'USA-US203-2020-MRNA-1273-P301000006'	System	24 Nov 2020 20:39:57

**US3342200**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:00:19**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'Yes (Y)'	System	24 Nov 2020 20:39:57

**US3342200**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:00:19**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

**US3342200**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:00:19**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

**US3342200**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:00:19**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

**US3342200**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:00:19**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

**US3342200**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:00:19**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'No (N)'	System	24 Nov 2020 20:39:57

**US3342200**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:00:19**

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:40:18
User entered 'Yes (Y)'	System	24 Nov 2020 20:39:57



**US3342200**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:00:19**

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	24 Nov 2020 20:40:28

**US3342200**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 11:00:19**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Nov 2020 20:40:28

**US3342200**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000006**

**Form: Safety Report Form (1)**

**Generated On: 26 Nov 2020 11:00:19**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '24/Nov/2020 20:40'	System	24 Nov 2020 20:40:28

US3342200

Folder: SAE USA-US203-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:00:19

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 20:40:28