

US3272169 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:52:38

All time stamps listed in this document are displayed in GMT

**US3272169**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 10:52:38**

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[Participant ID](#)

US3272169

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

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US3272169

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:52:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3272169

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:38

Date of Birth (MMM yyyy)	(b) (6) 1973
Age	47
Age Units	YEARS
Age (Derived)	47
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3272169

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:52:38

Date of Informed Consent ( <i>dd MMM yyyy</i> )	15 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:52:38

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 26 Nov 2020 10:52:38**

[Were any significant conditions reported?](#)

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:52:38

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



US3272169

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:52:38

Condition	ARRHYTHMIA (IRREGULAR HEART BEAT) (ATRIAL FIBRILLATION)
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3272169

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:52:38

Condition	NEUROPATHY IN NECK (SENSORY)
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

US3272169

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:52:38

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 1997
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 1997
Start Year (derived)	1997
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:52:38

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Start Year (derived)	1975
Stop Month and Year (derived)	
Stop Year (derived)	

US3272169

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:52:38

Condition	OVERACTIVE BLADDER
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3272169

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:52:38

Condition	FULL HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1999
Start Year (derived)	1999
Stop Month and Year (derived)	JAN 1999
Stop Year (derived)	1999

US3272169

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:52:38

Condition	ENDOMETRIOSIS
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1999
Start Year (derived)	1999
Stop Month and Year (derived)	JAN 1999
Stop Year (derived)	1999

US3272169

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:52:38

Condition	ALLERGY TO ASPIRIN
Start date (dd MMM yyyy)	UN UNK 1994
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 1994
Start Year (derived)	1994
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:52:38

Condition	ALLERGY TO CODEINE
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)	

US3272169

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:52:38

Condition	ALLERGY TO MORPHINE
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	
Stop Year (derived)	

US3272169

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:52:38

Condition	ALLERGY TO IODINE
Start date (dd MMM yyyy)	UN UNK 1994
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 1994
Start Year (derived)	1994
Stop Month and Year (derived)	
Stop Year (derived)	

US3272169

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:52:38

Condition	ALLERGY TO TORADOL
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	
Stop Year (derived)	

US3272169

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:52:38

Condition	ALLERGY TO DILAUDID
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3272169

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:52:38

Condition	ANTERIOR FUSION 3-7 PSEUDOARTHROSIS (C4-C7)
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

US3272169

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:52:38

Condition	LEFT HIP GRAFT
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

US3272169

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 10:52:38

Condition	CATARACT (LEFT EYE)
Start date (dd MMM yyyy)	UN UNK 2013
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 MAY 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	MAY 2014
Stop Year (derived)	2014



US3272169

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:52:38

Condition	VITREOUS HUMOR (LEFT EYE)
Start date (dd MMM yyyy)	UN MAY 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)	8 OCT 2020
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	OCT 2020
Stop Year (derived)	2020

US3272169

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	15 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	13:55 (24 HR)
Vital Signs Date and Time (derived)	15 AUG 2020 13:55
Height ( <i>xxx.x</i> )	173.5 cm
Weight ( <i>xxx.x</i> )	59.7 kg
BMI ( <i>xxx.x</i> )	19.83240 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)	

US3272169

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:38

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: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:52:38

Date of assessment ( <i>dd MMM yyyy</i> )	15 AUG 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> )	UN UNK 1999
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 10:52:38

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**Occupational Risk**

<b>Healthcare workers</b> (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes <input checked="" type="radio"/>	No <input 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 checked="" type="radio"/>	No <input 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**

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**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

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:38

<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>	

US3272169

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:52:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3272169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:52:38

What was the date of randomization? (dd MMM yyyy) 15 AUG 2020

What was the participant's randomization number? 104796

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 ☐



**US3272169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 26 Nov 2020 10:52:38**

Height	ND - Not Done
Weight	ND - Not Done

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:38

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)	15 AUG 2020
Time of assessment (00:00-23:59)	13:55 (24 HR)
Vital Signs Date and Time (derived)	15 AUG 2020 13:55
Temperature (xxx.x)	37 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:38

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)	15 AUG 2020
Time of assessment (00:00-23:59)	15:22 (24 HR)
Vital Signs Date and Time (derived)	15 AUG 2020 15:22
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3272169

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 AUG 2020

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

US3272169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:52:38

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 15 AUG 2020

What was the treatment time? (00:00-23:59) 14:52 (24 HR)

Treatment Date and Time (derived) 15 AUG 2020 14:52

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

What was the frequency of the study treatment dosing? ONCE

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

US3272169

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	15 AUG 2020
Collection time ( <i>00:00-23:59</i> )	14:15 (24 HR)
Collection date and time (derived)	15 AUG 2020 14:15

US3272169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:52:38

Collection date ( <i>dd MMM yyyy</i> )			15 AUG 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:04	15 AUG 2020 14:04
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:52:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3272169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐  
No ☒

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

PC Time Stamp 15 AUG 2020 15:16

PC Open Date & Time 15 AUG 2020 15:12

PC Close Date & Time 15 AUG 2020 17:42

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:52:38

**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

98.7 °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 15 AUG 2020 21:03

PC Open Date & Time 15 AUG 2020 18:37

PC Close Date & Time 16 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:52:38

**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 ☒

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

16 AUG 2020 15:56

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.6 °F
Was any <b>MEDICATION TAKEN today for pain or fever</b> ?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	17 AUG 2020 21:50
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:52:38

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.0 °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

18 AUG 2020 23:41

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PC Open Date & Time

18 AUG 2020 12:00

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PC Close Date & Time

19 AUG 2020 11:59

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US3272169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:52:38

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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

98.2 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

19 AUG 2020 22:14

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PC Open Date & Time

19 AUG 2020 12:00

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PC Close Date & Time

20 AUG 2020 11:59

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US3272169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:52:38

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.0 °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

20 AUG 2020 21:38

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PC Open Date & Time

20 AUG 2020 12:00

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PC Close Date & Time

21 AUG 2020 11:59

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US3272169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:52:38

**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

99.9 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

22 AUG 2020 00:04

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59



US3272169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 8

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.9 °F
Was any <b>MEDICATION TAKEN today for pain or fever?</b>	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	22 AUG 2020 21:46
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 26 Nov 2020 10:52:38

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**TIMEPOINT**

DAY 9

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

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 23:42

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:52:38

**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

15 AUG 2020 15:17

PC Open Date & Time

15 AUG 2020 15:12

PC Close Date & Time

15 AUG 2020 17:42

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:52:38

**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

15 AUG 2020 21:05

PC Open Date & Time

15 AUG 2020 18:37

PC Close Date & Time

16 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:52:38

**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

16 AUG 2020 15:57

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:52:38

**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

17 AUG 2020 21:50

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:52:38

**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

18 AUG 2020 23:42

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:52:38

**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

19 AUG 2020 22:14

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59



US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:52:38

**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

20 AUG 2020 21:38

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:52:38

**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

22 AUG 2020 00:04

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:52:38

**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 ☐

US3272169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:52:38

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

No ☒

Yes ☐

PC Time stamp	15 AUG 2020 15:17
PC Open Date & Time	15 AUG 2020 15:12
PC Close Date & Time	15 AUG 2020 17:42

US3272169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:52:38

**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 ☐

US3272169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:52:38

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

No ☒

Yes ☐

PC Time stamp	15 AUG 2020 21:04
PC Open Date & Time	15 AUG 2020 18:37
PC Close Date & Time	16 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:52:38

**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 ☒

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 15:57
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59



US3272169

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:52:38

**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 ☒

US3272169

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:52:38

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 21:51
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:52:38

**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 ☒

US3272169

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:52:38

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 23:43
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:52:38

**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 ☒

US3272169

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:52:38

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 22:14
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:52:38

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 ☒

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

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



US3272169

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:52:38

**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 ☒

US3272169

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:52:38

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 00:05
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 26 Nov 2020 10:52:38

**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 22 AUG 2020 21:46

PC Open Date & Time 22 AUG 2020 12:00

PC Close Date & Time 23 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 26 Nov 2020 10:52:38

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**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 ☐

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PC Time Stamp	23 AUG 2020 23:42
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PC Open Date & Time	23 AUG 2020 12:00
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PC Close Date & Time	24 AUG 2020 11:59
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US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 26 Nov 2020 10:52:38

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

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(11)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 11

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 25 AUG 2020 23:56

PC Open Date & Time 25 AUG 2020 12:00

PC Close Date & Time 26 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(12)

Generated On: 26 Nov 2020 10:52:38

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

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(13)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 13

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

28 AUG 2020 00:30

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59



US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(14)

Generated On: 26 Nov 2020 10:52:38

**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 29 AUG 2020 00:35

PC Open Date & Time 28 AUG 2020 12:00

PC Close Date & Time 29 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(15)

Generated On: 26 Nov 2020 10:52:38

**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 29 AUG 2020 21:39

PC Open Date & Time 29 AUG 2020 12:00

PC Close Date & Time 30 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 26 Nov 2020 10:52:38

<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	22 AUG 2020 21:46
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 26 Nov 2020 10:52:38

<b>TIMEPOINT</b>	DAY 9
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 AUG 2020 23:42
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 26 Nov 2020 10:52:38

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

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 26 Nov 2020 10:52:38

<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	25 AUG 2020 23:57
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 26 Nov 2020 10:52:38

<b>TIMEPOINT</b>	DAY 12
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 26 Nov 2020 10:52:38

<b>TIMEPOINT</b>	DAY 13
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 AUG 2020 00:31
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59



US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 26 Nov 2020 10:52:38

<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	29 AUG 2020 00:35
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(15)

Generated On: 26 Nov 2020 10:52:38

<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	29 AUG 2020 21:39
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3272169

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:38

Was Contact Attempted?

Yes ☒

No ☐

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

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3272169

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3272169**

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

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

Was Contact Attempted?

Yes ☒

No ☐

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

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3272169

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272169

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:38

Was Contact Attempted?

Yes ☒

No ☐

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

08 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3272169

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3272169

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:52:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:38

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)	16 SEP 2020
Time of assessment (00:00-23:59)	11:15 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 11:15
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	84 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:38

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)	16 SEP 2020
Time of assessment (00:00-23:59)	12:26 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 12:26
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	81 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3272169

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 2020

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

US3272169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:52:38

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)	16 SEP 2020
What was the treatment time? (00:00-23:59)	12:06 (24 HR)
Treatment Date and Time (derived)	16 SEP 2020 12:06
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

US3272169

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	16 SEP 2020
Collection time ( <i>00:00-23:59</i> )	11:20 (24 HR)
Collection date and time (derived)	16 SEP 2020 11:20

US3272169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:52:38

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:25	16 SEP 2020 11:25
Nasopharyngeal Swab 2	No		

US3272169

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 12:28

PC Open Date & Time

16 SEP 2020 12:26

PC Close Date & Time

16 SEP 2020 14:56

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:52:38

**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 98.9 °F

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

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

PC Time Stamp	16 SEP 2020 21:48
PC Open Date & Time	16 SEP 2020 15:51
PC Close Date & Time	17 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.1 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

17 SEP 2020 21:24

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	99.3 °F
Was any <b>MEDICATION TAKEN today for pain or fever</b> ?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	18 SEP 2020 23:39
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.7 °F
Was any <b>MEDICATION TAKEN today for pain or fever</b> ?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	19 SEP 2020 21:49
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:52:38

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.9 °F
Was any <b>MEDICATION TAKEN today for pain or fever</b> ?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	20 SEP 2020 23:58
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:52:38

**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

99.0 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

21 SEP 2020 21:31

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:52:38

**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.

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

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

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

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

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

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

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

PC Time Stamp	22 SEP 2020 23:19
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59



US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 8

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.

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.9 °F
Was any <b>MEDICATION TAKEN today for pain or fever</b> ?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	23 SEP 2020 21:59
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 9

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

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

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

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

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

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

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

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

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

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

PC Time Stamp	24 SEP 2020 22:32
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(10)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 10

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.

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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.

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	99.9 °F
Was any <b>MEDICATION TAKEN today for pain or fever</b> ?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	25 SEP 2020 23:20
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(11)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 11

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.

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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.

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.7 °F
Was any <b>MEDICATION TAKEN today for pain or fever</b> ?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	26 SEP 2020 21:31
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(12)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 12

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.

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.8 °F
Was any <b>MEDICATION TAKEN today for pain or fever?</b>	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	27 SEP 2020 23:52
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(13)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 13

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.9 °F
Was any <b>MEDICATION TAKEN today for pain or fever?</b>	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	28 SEP 2020 21:15
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(14)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 14

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.9 °F
Was any <b>MEDICATION TAKEN today for pain or fever</b> ?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	29 SEP 2020 22:18
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(15)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 15

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.7 °F
Was any <b>MEDICATION TAKEN today for pain or fever</b> ?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	30 SEP 2020 20:03
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59



US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(16)

Generated On: 26 Nov 2020 10:52:38

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**TIMEPOINT**

DAY 16

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 22:27

---

PC Open Date & Time

01 OCT 2020 12:00

---

PC Close Date & Time

02 OCT 2020 11:59

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US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:52:38

**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

16 SEP 2020 13:05

PC Open Date & Time

16 SEP 2020 12:26

PC Close Date & Time

16 SEP 2020 14:56

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:52:38

**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

16 SEP 2020 21:49

PC Open Date & Time

16 SEP 2020 15:51

PC Close Date & Time

17 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:52:38

**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

17 SEP 2020 21:25

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:52:38

**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

18 SEP 2020 23:39

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:52:38

**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

19 SEP 2020 21:49

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:52:38

**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

20 SEP 2020 23:58

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:52:38

**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

21 SEP 2020 21:32

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59



US3272169

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:52:38

**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

22 SEP 2020 23:20

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:52:38

**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 ☐

US3272169

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:52:38

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 13:05
PC Open Date & Time	16 SEP 2020 12:26
PC Close Date & Time	16 SEP 2020 14:56

US3272169

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:52:38

**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 ☐

US3272169

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:52:38

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 21:49
PC Open Date & Time	16 SEP 2020 15:51
PC Close Date & Time	17 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:52:38

**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 ☒

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 21:25
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:52:38

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 ☒



**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 23:39
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:52:38

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 ☒

US3272169

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:52:38

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 21:49
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:52:38

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 ☒

US3272169

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:52:38

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 23:59
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:52:38

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 ☒

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 21:32
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:52:38

**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 ☒



**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 23:20
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

**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 ☐

PC Time Stamp 23 SEP 2020 22:00

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Headache\_Day(9)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

**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 ☐

PC Time Stamp 24 SEP 2020 22:32

PC Open Date & Time 24 SEP 2020 12:00

PC Close Date & Time 25 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Headache\_Day(10)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your

**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 ☐

PC Time Stamp 25 SEP 2020 23:21

PC Open Date & Time 25 SEP 2020 12:00

PC Close Date & Time 26 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Headache\_Day(11)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 11

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 21:31

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Headache\_Day(12)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 12

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 23:52

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Headache\_Day(13)

Generated On: 26 Nov 2020 10:52:38

---

**TIMEPOINT**

DAY 13

Select one response below to indicate the intensity of your

**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 ☐

---

PC Time Stamp 28 SEP 2020 21:16

PC Open Date & Time 28 SEP 2020 12:00

---

PC Close Date & Time 29 SEP 2020 11:59

---

US3272169

Folder: Diary Dose 2 (1)

Form: Headache\_Day(14)

Generated On: 26 Nov 2020 10:52:38

---

**TIMEPOINT**

DAY 14

Select one response below to indicate the intensity of your

**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 ☐

---

PC Time Stamp 29 SEP 2020 22:18

PC Open Date & Time 29 SEP 2020 12:00

---

PC Close Date & Time 30 SEP 2020 11:59

---



US3272169

Folder: Diary Dose 2 (1)

Form: Headache\_Day(15)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 15

Select one response below to indicate the intensity of your

**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 ☐

PC Time Stamp 30 SEP 2020 20:03

PC Open Date & Time 30 SEP 2020 12:00

PC Close Date & Time 01 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Headache\_Day(16)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 16

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 22:27

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Headache\_Day(17)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 17

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Headache\_Day(18)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 18

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 22:22

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Headache\_Day(19)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 19

Select one response below to indicate the intensity of your

**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 ☐

PC Time Stamp 04 OCT 2020 23:46

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Headache\_Day(20)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 20

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Headache\_Day(21)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 21

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 00:07

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 26 Nov 2020 10:52:38

**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 23 SEP 2020 22:00

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59



US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 26 Nov 2020 10:52:38

---

**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

24 SEP 2020 22:32

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

---

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(10)

Generated On: 26 Nov 2020 10:52:38

**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

25 SEP 2020 23:21

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(11)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 11

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

26 SEP 2020 21:32

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(12)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 12

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

27 SEP 2020 23:52

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(13)

Generated On: 26 Nov 2020 10:52:38

---

**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

28 SEP 2020 21:16

---

PC Open Date & Time

28 SEP 2020 12:00

---

PC Close Date & Time

29 SEP 2020 11:59

---

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(14)

Generated On: 26 Nov 2020 10:52:38

**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

29 SEP 2020 22:19

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(15)

Generated On: 26 Nov 2020 10:52:38

---

**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

30 SEP 2020 20:04

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

---

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(16)

Generated On: 26 Nov 2020 10:52:38

**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 01 OCT 2020 22:27

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59



US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(17)

Generated On: 26 Nov 2020 10:52:38

**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

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(18)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 18

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 03 OCT 2020 22:22

PC Open Date & Time 03 OCT 2020 12:00

PC Close Date & Time 04 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(19)

Generated On: 26 Nov 2020 10:52:38

---

**TIMEPOINT**

DAY 19

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 04 OCT 2020 23:46

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

---

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(20)

Generated On: 26 Nov 2020 10:52:38

TIMEPOINT

DAY 20

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

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(21)

Generated On: 26 Nov 2020 10:52:38

---

**TIMEPOINT**

DAY 21

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 00:07

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

---

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(22)

Generated On: 26 Nov 2020 10:52:38

---

**TIMEPOINT**

DAY 22

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

07 OCT 2020 21:04

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

---

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(23)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 23

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

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(24)

Generated On: 26 Nov 2020 10:52:38

---

**TIMEPOINT**

DAY 24

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 22:02

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

---



US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(25)

Generated On: 26 Nov 2020 10:52:38

---

**TIMEPOINT**

DAY 25

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 10 OCT 2020 22:53

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

---

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(26)

Generated On: 26 Nov 2020 10:52:38

---

**TIMEPOINT**

DAY 26

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

12 OCT 2020 00:04

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

---

US3272169

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(27)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 27

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 12 OCT 2020 22:33

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 26 Nov 2020 10:52:38

**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 23 SEP 2020 22:00

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(9)

Generated On: 26 Nov 2020 10:52:38

**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 ☐

PC Time stamp 24 SEP 2020 22:32

PC Open Date & Time 24 SEP 2020 12:00

PC Close Date & Time 25 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(10)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 10

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 25 SEP 2020 23:21

PC Open Date & Time 25 SEP 2020 12:00

PC Close Date & Time 26 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(11)

Generated On: 26 Nov 2020 10:52:38

**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 26 SEP 2020 21:32

PC Open Date & Time 26 SEP 2020 12:00

PC Close Date & Time 27 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(12)

Generated On: 26 Nov 2020 10:52:38

**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 27 SEP 2020 23:53

PC Open Date & Time 27 SEP 2020 12:00

PC Close Date & Time 28 SEP 2020 11:59



US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(13)

Generated On: 26 Nov 2020 10:52:38

**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 28 SEP 2020 21:16

PC Open Date & Time 28 SEP 2020 12:00

PC Close Date & Time 29 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(14)

Generated On: 26 Nov 2020 10:52:38

---

**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 ☐

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PC Time stamp 29 SEP 2020 22:19

PC Open Date & Time 29 SEP 2020 12:00

PC Close Date & Time 30 SEP 2020 11:59

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US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(15)

Generated On: 26 Nov 2020 10:52:38

TIMEPOINT

DAY 15

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

30 SEP 2020 20:04

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(16)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 16

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 01 OCT 2020 22:27

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(17)

Generated On: 26 Nov 2020 10:52:38

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

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(18)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 18

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 03 OCT 2020 22:23

PC Open Date & Time 03 OCT 2020 12:00

PC Close Date & Time 04 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(19)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 19

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 04 OCT 2020 23:46

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(20)

Generated On: 26 Nov 2020 10:52:38

TIMEPOINT

DAY 20

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

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59



US3272169

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(21)

Generated On: 26 Nov 2020 10:52:38

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**TIMEPOINT**

DAY 21

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 07 OCT 2020 00:07

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

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US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 26 Nov 2020 10:52:38

**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 23 SEP 2020 22:00

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(9)

Generated On: 26 Nov 2020 10:52:38

---

**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	24 SEP 2020 22:32
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PC Open Date & Time	24 SEP 2020 12:00
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PC Close Date & Time	25 SEP 2020 11:59
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US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(10)

Generated On: 26 Nov 2020 10:52:38

**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 25 SEP 2020 23:21

PC Open Date & Time 25 SEP 2020 12:00

PC Close Date & Time 26 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(11)

Generated On: 26 Nov 2020 10:52:38

---

**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 26 SEP 2020 21:32

PC Open Date & Time 26 SEP 2020 12:00

PC Close Date & Time 27 SEP 2020 11:59

---

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(12)

Generated On: 26 Nov 2020 10:52:38

**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 27 SEP 2020 23:53

PC Open Date & Time 27 SEP 2020 12:00

PC Close Date & Time 28 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(13)

Generated On: 26 Nov 2020 10:52:38

**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 28 SEP 2020 21:16

PC Open Date & Time 28 SEP 2020 12:00

PC Close Date & Time 29 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(14)

Generated On: 26 Nov 2020 10:52:38

**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 29 SEP 2020 22:19

PC Open Date & Time 29 SEP 2020 12:00

PC Close Date & Time 30 SEP 2020 11:59



US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(15)

Generated On: 26 Nov 2020 10:52:38

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

30 SEP 2020 20:04

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(16)

Generated On: 26 Nov 2020 10:52:38

---

**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 01 OCT 2020 22:27

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

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US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(17)

Generated On: 26 Nov 2020 10:52:38

**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

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(18)

Generated On: 26 Nov 2020 10:52:38

**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 03 OCT 2020 22:23

PC Open Date & Time 03 OCT 2020 12:00

PC Close Date & Time 04 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(19)

Generated On: 26 Nov 2020 10:52:38

**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 04 OCT 2020 23:47

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(20)

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 20

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

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(21)

Generated On: 26 Nov 2020 10:52:38

---

**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 ☐

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PC Time stamp	07 OCT 2020 00:07
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PC Open Date & Time	06 OCT 2020 12:00
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PC Close Date & Time	07 OCT 2020 11:59
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US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 26 Nov 2020 10:52:38

<b>TIMEPOINT</b>	DAY 8
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	23 SEP 2020 22:01
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59



US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 26 Nov 2020 10:52:38

<b>TIMEPOINT</b>	DAY 9
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 SEP 2020 22:32
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 26 Nov 2020 10:52:38

<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	25 SEP 2020 23:21
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 26 Nov 2020 10:52:38

<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	26 SEP 2020 21:32
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(12)

Generated On: 26 Nov 2020 10:52:38

<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	27 SEP 2020 23:53
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(13)

Generated On: 26 Nov 2020 10:52:38

<b>TIMEPOINT</b>	DAY 13
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	28 SEP 2020 21:16
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(14)

Generated On: 26 Nov 2020 10:52:38

<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	29 SEP 2020 22:19
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(15)

Generated On: 26 Nov 2020 10:52:38

<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	30 SEP 2020 20:04
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(16)

Generated On: 26 Nov 2020 10:52:38

<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	01 OCT 2020 22:28
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59



US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(17)

Generated On: 26 Nov 2020 10:52:38

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

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(18)

Generated On: 26 Nov 2020 10:52:38

<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	03 OCT 2020 22:23
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(19)

Generated On: 26 Nov 2020 10:52:38

<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	04 OCT 2020 23:47
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(20)

Generated On: 26 Nov 2020 10:52:38

<b>TIMEPOINT</b>	DAY 20
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(21)

Generated On: 26 Nov 2020 10:52:38

<b>TIMEPOINT</b>	DAY 21
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 00:07
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(23)

Generated On: 26 Nov 2020 10:52:38

<b>TIMEPOINT</b>	DAY 23
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(24)

Generated On: 26 Nov 2020 10:52:38

<b>TIMEPOINT</b>	DAY 24
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	09 OCT 2020 22:02
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(25)

Generated On: 26 Nov 2020 10:52:38

<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	10 OCT 2020 22:53
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59



US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(26)

Generated On: 26 Nov 2020 10:52:38

<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	12 OCT 2020 00:04
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(27)

Generated On: 26 Nov 2020 10:52:38

<b>TIMEPOINT</b>	DAY 27
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	12 OCT 2020 22:33
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

**US3272169**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

Was Contact Attempted?

Yes ☒

No ☐

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

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3272169

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272169

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:38

Was Contact Attempted?

Yes ☒

No ☐

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

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3272169

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272169

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:38

Was Contact Attempted?

Yes ☒

No ☐

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

08 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3272169

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3272169

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:52:38

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

US3272169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	14 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	10:45 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 10:45
Temperature ( <i>xxx.x</i> )	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	82 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	88 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3272169

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 OCT 2020

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

US3272169

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	14 OCT 2020
Collection time ( <i>00:00-23:59</i> )	11:10 (24 HR)
Collection date and time (derived)	14 OCT 2020 11:10

US3272169

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**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

15 OCT 2020 21:35:16

Patient Cloud Open Date & Time

15 OCT 2020 00:01

Patient Cloud Close Date & Time

19 OCT 2020 23:59

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**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

22 OCT 2020 00:59:38

Patient Cloud Open Date & Time

22 OCT 2020 00:01

Patient Cloud Close Date & Time

26 OCT 2020 23:59

US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**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

29 OCT 2020 22:27:09

Patient Cloud Open Date & Time

29 OCT 2020 00:01

Patient Cloud Close Date & Time

02 NOV 2020 23:59



US3272169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	12 NOV 2020 21:10:14
Patient Cloud Open Date & Time	12 NOV 2020 00:01
Patient Cloud Close Date & Time	16 NOV 2020 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 OCT 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 OCT 2020 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

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30 OCT 2020 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

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06 NOV 2020 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Open Date & Time](#)

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09 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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13 NOV 2020 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 NOV 2020 21:13:17
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 NOV 2020 22:17:26

Patient Cloud Open Date & Time

23 NOV 2020 00:01

Patient Cloud Close Date & Time

27 NOV 2020 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

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04 DEC 2020 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>



**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 DEC 2020 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Open Date & Time](#)

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14 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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18 DEC 2020 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

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25 DEC 2020 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 138

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

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

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

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

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

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

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

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

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

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01 JAN 2021 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>



**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

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08 JAN 2021 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 152

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

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

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

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

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

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

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

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

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**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 ☐ 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 ☐

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Open Date & Time](#)

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25 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 JAN 2021 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>



**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Open Date & Time](#)

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01 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 FEB 2021 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

12 FEB 2021 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

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26 FEB 2021 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>



**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

05 MAR 2021 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

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12 MAR 2021 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 215

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

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

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

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

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

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

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

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

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

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26 MAR 2021 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>



**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	29 MAR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 APR 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

05 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

09 APR 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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="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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Open Date & Time](#)

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12 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 APR 2021 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Open Date & Time](#)

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19 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 APR 2021 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**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 ☐



**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

[Patient Cloud Close Date & Time](#)

30 APR 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Open Date & Time](#)

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03 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 MAY 2021 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

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14 MAY 2021 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

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21 MAY 2021 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**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 ☐  
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 ☐



**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

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28 MAY 2021 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

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

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

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**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 ☐ 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 ☐

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Open Date & Time](#)

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14 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 JUN 2021 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>



**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

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25 JUN 2021 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

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

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

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>



**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Open Date & Time](#)

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19 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 JUL 2021 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**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 ☐  
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 ☐

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

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30 JUL 2021 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**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 ☐

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**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 ☐  
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 ☐

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Open Date & Time](#)

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09 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 AUG 2021 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**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 ☐



**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	23 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	27 AUG 2021 23:59
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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

30 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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°F/38°C) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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

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



**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Open Date & Time](#)

13 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Open Date & Time](#)

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04 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 OCT 2021 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>



**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

[Patient Cloud Close Date & Time](#)

15 OCT 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**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 ☐  
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 ☐

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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



**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

22 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Open Date & Time](#)

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29 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 DEC 2021 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**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 ☐  
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 ☐



**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

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17 DEC 2021 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**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 ☐  
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 ☐

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

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24 DEC 2021 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**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 ☐

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**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 ☐



**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Open Date & Time](#)

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03 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 JAN 2022 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

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14 JAN 2022 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**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 ☐

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

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

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

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Open Date & Time](#)

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24 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 JAN 2022 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

TIMEPOINT

DAY 537

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐



**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Open Date & Time](#)

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31 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 FEB 2022 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

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

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

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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 ☐

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Open Date & Time](#)

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14 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 FEB 2022 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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 ☐

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Open Date & Time](#)

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21 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 FEB 2022 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**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 ☐



**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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 ☐

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Open Date & Time](#)

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07 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAR 2022 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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 ☐

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Open Date & Time](#)

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14 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAR 2022 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

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25 MAR 2022 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**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 ☐



**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

[Patient Cloud Open Date & Time](#)

28 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

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08 APR 2022 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 APR 2022 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Open Date & Time](#)

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18 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 APR 2022 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>



**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 APR 2022 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**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 ☐  
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 ☐

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Open Date & Time](#)

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09 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 MAY 2022 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

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20 MAY 2022 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

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27 MAY 2022 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Open Date & Time](#)

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30 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 JUN 2022 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**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 ☐

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Open Date & Time](#)

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06 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 JUN 2022 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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 ☐



**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

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24 JUN 2022 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

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01 JUL 2022 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUL 2022 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>



**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Open Date & Time](#)

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25 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 JUL 2022 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

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12 AUG 2022 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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



**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this 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 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2022 23:59
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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

22 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

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02 SEP 2022 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

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

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

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**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 ☐

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 ☐



**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Open Date & Time](#)

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19 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 SEP 2022 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**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 ☐

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Close Date & Time](#)

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30 SEP 2022 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

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[Patient Cloud Open Date & Time](#)

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03 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 OCT 2022 23:59

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US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

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

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



**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

US3272169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:38

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"/>

**US3272169**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

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

---

Date and time of submission

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[Patient Cloud Open Date & Time](#)

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17 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 OCT 2022 23:59

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**US3272169**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

Was Contact Attempted?

Yes ☒

No ☐

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

13 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3272169

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3272169**

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

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

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*

**US3272169**

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

**Form: Continuing**

**Generated On: 26 Nov 2020 10:52:38**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:52:38

Date of Contact	28 SEP 2020
Time of Contact	08:00
Date and Time of Contact (derived)	28 SEP 2020 08:00
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/>
	Clinical Visit - Unscheduled <input type="radio"/>
	Safety Call <input type="radio"/>
	Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>



US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:38

Symptom Day

Day 1	<input checked="" type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:38

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	36.8 C	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	457 of 2878	

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:38

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

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:38

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

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:52:38

Date of Visit	28 SEP 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	28 SEP 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	_____
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

**US3272169**

**Folder: Covid-19 Assessment 28 Sep 2020**

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

**Generated On: 26 Nov 2020 10:52:38**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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**US3272169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection**

**Generated On: 26 Nov 2020 10:52:38**

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	30 SEP 2020
Day 5	Yes	2 OCT 2020
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3272169

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:52:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1



US3272169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	28 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	15:18 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 15:18
Height ( <i>xxx.x</i> )	175 cm
Weight ( <i>xxx.x</i> )	135.6 kg
Temperature ( <i>xxx.x</i> )	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	76 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	95 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3272169

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3272169

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:52:38

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

28 SEP 2020

**US3272169**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:52:38**

Was this visit performed? Yes ☐  
No ☐

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

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

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

US3272169

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:38

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

US3272169

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:38

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.*

**US3272169**

**Folder: Convalescence Visit Day 28 (1)**

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

**Generated On: 26 Nov 2020 10:52:38**

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
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US3272169

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:52:38

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Did the participant experience any adverse events?

Yes ☒

No ☐

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If Yes, enter details on the Adverse Events form.

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US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:38

AEID	
Adverse event	GASTROENTERITIS
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 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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)

472 of 2878

US3272169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:38

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:38

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)	16 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	2 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	474 of 2878

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:38

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

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:38

AEID	
Adverse event	GENERALIZED MUSCLE ACHES
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)	17 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	3 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)	476 of 2878

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:38

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

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:38

AEID	
Adverse event	HEADACHE
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)	16 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	1 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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)	478 of 2878

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:38

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



US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:38

AEID	USA-US070-2020-MRNA-1273-P30 1000018
Adverse event	RECTAL PROLAPSE
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)	8 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	8 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	19 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	24 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
v6.020 DTW (1102)	480 of 2878

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:38

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

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:38

---

PATIENT DISCLOSED AT DAY  
85 PHONE CALL ON 13NOV2020  
SHE HAD A RECTAL PROLAPSE  
THAT STARTED OCT08SEP2020  
WHEN SHE RECEIVED A  
ROUTINE COLONOSCOPY AND  
THEN HAD A RECTAL  
PROLAPSE REPAIR ON  
19OCT2020 AND WAS  
INPATIENT FROM 19OCT2020  
TO 24OCT2020 THEN HAD  
COMPLICATIONS AND WAS  
INPATIENT AGAIN FROM  
05NOV2020 TO 07NOV2020

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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US3272169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:38

AEID	USA-US070-2020-MRNA-1273-P30 1000018
Adverse event	RECTAL PROLAPSE REPAIR COMPLICATION DUE TO CONSTIPATION
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)	5 NOV 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)	7 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	5 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	7 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
v6.020 DTW (1102)	483 of 2878

US3272169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:38

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

US3272169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:38

---

PATIENT DISCLOSED AT DAY  
85 PHONE CALL ON 13NOV2020  
SHE HAD A RECTAL PROLAPSE  
THAT STARTED OCT08SEP2020  
WHEN SHE RECEIVED A  
ROUTINE COLONOSCOPY AND  
THEN HAD A RECTAL  
PROLAPSE REPAIR ON  
19OCT2020 AND WAS  
INPATIENT FROM 19OCT2020  
TO 24OCT2020 THEN HAD  
COMPLICATIONS AND WAS  
INPATIENT AGAIN FROM  
05NOV2020 TO 07NOV2020

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:52:38

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

Yes ☒

No ☐

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

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US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:38

Name of Medication	CELEXAS
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DEPRESSION
Dose per administration	20
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>



US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:38

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:38

Name of Medication	VRAYLAR
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DEPRESSION
Dose per administration	1.5
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:38

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

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:38

Name of Medication	VESLCARE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	OVERACTIVE BLADDER
Dose per administration	5
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:38

	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 2019
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:38

Name of Medication	LYRICA
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	NEUROPATHY IN NECK
Dose per administration	50
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:38

	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 2014
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:52:38

Name of Medication	METOPROLOL ER
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	ARRHYTHMIA (IRREGULAR HEART BEAT) ATRIAL FIBRILLATION
Dose per administration	25
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/>



US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:52:38

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

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:52:38

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

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:52:38

	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 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:52:38

Name of Medication	PRILOSEC
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	GASTROESOPHAGEAL REFLUX DISEASE
Dose per administration	20
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:52:38

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

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:52:38

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

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:52:38

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

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:52:38

Name of Medication	VITAMIN E
Prophylaxis	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Indication	NUTRITIONAL SUPPLEMENT
Dose per administration	180
Dose unit	mg <input checked="" type="radio"/>
	ug <input type="radio"/>
	mL <input type="radio"/>
	g <input type="radio"/>
	IU <input type="radio"/>
	tablet <input type="radio"/>
	capsule <input type="radio"/>
	puff <input type="radio"/>
	Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/>
	twice daily <input checked="" type="radio"/>
	three times daily <input type="radio"/>
	four times daily <input type="radio"/>
	every other day <input type="radio"/>
	every week <input type="radio"/>
	every month <input type="radio"/>
	as needed <input type="radio"/>
	once <input type="radio"/>
	unknown <input type="radio"/>
	other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/>
	Topical <input type="radio"/>
	Subcutaneous <input type="radio"/>
	Transdermal <input type="radio"/>
	Intraocular <input type="radio"/>
	Intramuscular <input type="radio"/>



US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:52:38

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 JUN 2020
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input checked="" type="radio"/>

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:52:38

Name of Medication	TYLENOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	INJECTION SITE PAIN
Dose per administration	1000
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:52:38

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:52:38

Name of Medication	PREDNISOLONE ACETATE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	YAG LASER POSTERIOR CAPSULOTOMY (LEFT EYE)
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	DROP
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input checked="" type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:52:38

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	TOPICAL EYE	
Start date (dd MMM yyyy)	9 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	11 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:52:38

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 10:52:38

Procedure/Surgery date ( <i>dd MMM yyyy</i> )	Procedure/Surgery	Indication	If indication is Other, specify
19 OCT 2020	RECTAL PROLAPSE REPAIR	Adverse Event	
8 OCT 2020	YAG LASER POSTERIOR CAPSULOTOMY (LEFT EYE)	Medical History	

**US3272169**

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 26 Nov 2020 10:52:38**

---

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

---



US3272169

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:52:38

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 ☐

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:38

SAEID	USA-US070-2020-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:52:38

SAEID	USA-US070-2020-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	16/NOV/2020 10:32
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:52:38

SAEID	USA-US070-2020-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	24/NOV/2020 13:11
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

US3272169 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

**US3272169**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 10:52:38**

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3272169'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	15 Aug 2020 19:29:17

**US3272169**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:52:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:37:44

**US3272169**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '15 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	15 Aug 2020 19:29:18



**US3272169**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	15 Aug 2020 20:37:44

**US3272169**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:52:38**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	15 Aug 2020 20:37:44

**US3272169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered (b) (6) 1973'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	15 Aug 2020 19:29:19

**US3272169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:52:38**

[Age](#)

Audit	User	Time (GMT)
User entered '47'	(b) (4), (b) (6)	15 Aug 2020 20:38:32

**US3272169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:52:38**

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	15 Aug 2020 20:38:32

**US3272169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:52:38**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '47'	System	15 Aug 2020 20:07:12

**US3272169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:52:38**

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	(b) (4), (b) (6)	15 Aug 2020 20:38:32

**US3272169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:52:38**

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	15 Aug 2020 20:38:32



**US3272169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:52:38**

[White](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	15 Aug 2020 20:38:32

**US3272169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:52:38**

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:38:32

**US3272169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:52:38**

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:38:32

**US3272169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:52:38**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:38:32

**US3272169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:52:38**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:38:32

**US3272169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:52:38**

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:38:32

**US3272169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:52:38**

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:38:32

**US3272169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:52:38**

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:38:32



**US3272169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:52:38**

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:38:32

US3272169

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:52:38

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Aug 2020'	Kayla Flege (b) (4) (b) (4)	15 Aug 2020 20:07:12

**US3272169**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	15 Aug 2020 20:07:12

**US3272169**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '2020'	System	15 Aug 2020 20:07:12

**US3272169**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:52:38**

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	Kayla Flege (b) (4) (b) (4)	15 Aug 2020 20:07:12

US3272169

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:52:38

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	15 Aug 2020 20:07:12

**US3272169**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	15 Aug 2020 20:07:12

**US3272169**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:52:38**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	15 Aug 2020 20:07:12



**US3272169**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:52:38**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	15 Aug 2020 20:07:12

US3272169

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:52:38

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	15 Aug 2020 19:29:18

**US3272169**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:52:38**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Aug 2020 20:07:17

**US3272169**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	15 Aug 2020 20:07:17

**US3272169**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 26 Nov 2020 10:52:38**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:41:00

US3272169

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:52:38

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 20:43:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 20:43:15
Data point term sent to Coder	System	15 Aug 2020 20:42:09
User entered 'depression'	(b) (4), (b) (6) (b) (4)	15 Aug 2020 20:41:17

**US3272169**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	(b) (4), (b) (6)	15 Aug 2020 20:41:17

**US3272169**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:41:17



**US3272169**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:41:17

**US3272169**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:41:17

**US3272169**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:41:17

**US3272169**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	15 Aug 2020 20:41:17

**US3272169**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '2018'	System	15 Aug 2020 20:41:17

**US3272169**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 20:41:17

**US3272169**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 20:41:17

US3272169

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:52:38

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR RQ: Response to previous query noted as 'updated'. However, the TYPE OF ARRHYTHMIA (eg. Bradyarrhythmia, Supraventricular Arrhythmias, Atrial Fibrillation, etc.) was not specified. Please review and update medical history eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:19:19
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\23.0.	Coder Import (b) (4)	29 Oct 2020 22:25:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	29 Oct 2020 22:25:52
Query 'Per DM CLR RQ: Response to previous query noted as 'updated'. However, the TYPE OF ARRHYTHMIA (eg. Bradyarrhythmia, Supraventricular Arrhythmias, Atrial Fibrillation, etc.) was not specified. Please review and update medical history eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 15:39:10
Data point term sent to Coder	System	28 Oct 2020 15:39:07
Coding entries removed.	(b) (4), (b) (6)	28 Oct 2020 15:38:57
User entered 'ARRHYTHMIA (IRREGULAR HEART BEAT) (atrial fibrillation)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 15:38:57
User opened query 'Per DM CLR RQ: Response to previous query noted as 'updated'. However, the TYPE OF ARRHYTHMIA (eg. Bradyarrhythmia, Supraventricular Arrhythmias, Atrial Fibrillation, etc.) was not specified. Please review and update medical history eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 05:22:45
User closed query 'Per DM CLR: Please specify the type of Arrhythmia (eg, bradyarrhythmia, supraventricular arrhythmias, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 05:22:45



US3272169

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:52:38

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Arrhythmia, LLT: Arrhythmia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 00:22:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 00:22:53
Data point term sent to Coder	System	22 Sep 2020 00:21:29
Query 'Per DM CLR: Please specify the type of Arrhythmia (eg, bradyarrhythmia, supraventricular arrhythmias,etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	22 Sep 2020 00:20:36
' answered with 'updated' (Site from DM).		
Coding entries removed.	(b) (4), (b) (6)	22 Sep 2020 00:20:29
User entered 'ARRHYTHMIA (irregular heart beat)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 00:20:29
User opened query 'Per DM CLR: Please specify the type of Arrhythmia (eg, bradyarrhythmia, supraventricular arrhythmias,etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	21 Sep 2020 11:11:30
' (Site from DM).		
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Arrhythmia, LLT: Arrhythmia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 20:43:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 20:43:15
Data point term sent to Coder	System	15 Aug 2020 20:42:09
User entered 'arrhythmia'	(b) (4), (b) (6)	15 Aug 2020 20:41:34

**US3272169**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	(b) (4), (b) (6)	15 Aug 2020 20:41:34

**US3272169**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:41:34

**US3272169**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:41:34

**US3272169**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:41:34

**US3272169**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:41:34

**US3272169**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	15 Aug 2020 20:41:34

**US3272169**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '2018'	System	15 Aug 2020 20:41:34



**US3272169**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 20:41:34

**US3272169**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 20:41:34

US3272169

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:52:38

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:19:34
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Peripheral sensory neuropathy, LLT: Sensory neuropathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 13:12:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 13:12:52
Data point term sent to Coder	System	22 Sep 2020 00:23:30
Query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 00:23:00
User entered 'NEUROPATHY IN NECK (Sensory)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 00:22:53
User opened query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 11:11:52
Data point term sent to Coder	System	15 Aug 2020 20:42:09
User entered 'neuropathy in neck'	(b) (4), (b) (6)	15 Aug 2020 20:41:51

**US3272169**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'UN UNK 2013' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	25 Sep 2020 19:24:39
User entered 'UN UNK 2014' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	15 Aug 2020 20:42:30
User entered 'un UNK 2018'	(b) (4), (b) (6) (b) (4), (b) (6)	15 Aug 2020 20:41:51

**US3272169**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:41:51

**US3272169**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:41:51

**US3272169**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:41:51

**US3272169**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:41:51



**US3272169**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	25 Sep 2020 19:24:39
User entered 'Jan 2014'	System	15 Aug 2020 20:42:30
User entered 'Jan 2018'	System	15 Aug 2020 20:41:51

**US3272169**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '2013'	System	25 Sep 2020 19:24:39
User entered '2014'	System	15 Aug 2020 20:42:30
User entered '2018'	System	15 Aug 2020 20:41:51

**US3272169**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 20:41:51

**US3272169**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 20:41:51

US3272169

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:52:38

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 20:44:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 20:44:16
Data point term sent to Coder	System	15 Aug 2020 20:43:10
User entered 'gastroesophageal reflux disease'	(b) (4), (b) (6)	15 Aug 2020 20:42:19

**US3272169**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'un UNK 1997'	(b) (4), (b) (6)	15 Aug 2020 20:42:19

**US3272169**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:42:19

**US3272169**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:42:19



**US3272169**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:42:19

**US3272169**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:42:19

**US3272169**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'Jan 1997'	System	15 Aug 2020 20:42:19

**US3272169**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '1997'	System	15 Aug 2020 20:42:19

**US3272169**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 20:42:19

**US3272169**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 20:42:19

US3272169

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:52:38

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) (b) (4)	15 Aug 2020 20:44:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 20:44:16
Data point term sent to Coder	System	15 Aug 2020 20:43:12
User entered 'seasonal allergies'	(b) (4), (b) (6) (b) (4)	15 Aug 2020 20:42:44

**US3272169**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'un UNK 1975'	(b) (4), (b) (6)	15 Aug 2020 20:42:44



**US3272169**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:42:44

**US3272169**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:52:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:42:44

**US3272169**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:42:44

**US3272169**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:52:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:42:44

**US3272169**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'Jan 1975'	System	15 Aug 2020 20:42:44

**US3272169**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '1975'	System	15 Aug 2020 20:42:44

**US3272169**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 20:42:44

**US3272169**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 20:42:44



US3272169

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:52:38

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Bladder and bladder neck disorders (excl calculi), HLT: Myoneurogenic bladder disorders, PT: Hypertonic bladder, LLT: Overactive bladder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 20:44:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 20:44:16
Data point term sent to Coder	System	15 Aug 2020 20:43:14
User entered 'overactive bladder'	(b) (4), (b) (6) (b) (4)	15 Aug 2020 20:43:00

**US3272169**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	(b) (4), (b) (6)	15 Aug 2020 20:43:00

**US3272169**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:43:00

**US3272169**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:43:00

**US3272169**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:43:00

**US3272169**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:43:00

**US3272169**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	15 Aug 2020 20:43:00

**US3272169**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '2019'	System	15 Aug 2020 20:43:00



**US3272169**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 20:43:00

**US3272169**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 20:43:00

US3272169

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:52:38

[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)	15 Aug 2020 20:45:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 20:45:16
Data point term sent to Coder	System	15 Aug 2020 20:44:15
User entered 'full hysterectomy'	(b) (4), (b) (6) (b) (4)	15 Aug 2020 20:43:27

**US3272169**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'un UNK 1999'	(b) (4), (b) (6)	15 Aug 2020 20:43:27

**US3272169**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:43:27

**US3272169**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:43:27

**US3272169**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'un UNK 1999'	(b) (4), (b) (6)	15 Aug 2020 20:43:27

**US3272169**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:43:27



**US3272169**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'Jan 1999'	System	15 Aug 2020 20:43:27

**US3272169**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '1999'	System	15 Aug 2020 20:43:27

**US3272169**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'Jan 1999'	System	15 Aug 2020 20:43:27

**US3272169**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '1999'	System	15 Aug 2020 20:43:27

US3272169

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:52:38

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 20:46:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 20:46:17
Data point term sent to Coder	System	15 Aug 2020 20:45:16
User entered 'endometriosis'	(b) (4), (b) (6) (b) (4)	15 Aug 2020 20:45:02

**US3272169**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'un UNK 1999'	(b) (4), (b) (6)	15 Aug 2020 20:45:02

**US3272169**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:45:02

**US3272169**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:52:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:45:02



**US3272169**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'un UNK 1999'	(b) (4), (b) (6)	15 Aug 2020 20:45:02

**US3272169**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:52:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:45:02

**US3272169**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'Jan 1999'	System	15 Aug 2020 20:45:02

**US3272169**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '1999'	System	15 Aug 2020 20:45:02

**US3272169**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'Jan 1999'	System	15 Aug 2020 20:45:02

**US3272169**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '1999'	System	15 Aug 2020 20:45:02

US3272169

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:52:38

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: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 20:47:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 20:47:17
Data point term sent to Coder	System	15 Aug 2020 20:46:19
User entered 'allergy to aspirin'	(b) (4), (b) (6) (b) (4)	15 Aug 2020 20:45:19

**US3272169**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'un UNK 1994'	(b) (4), (b) (6)	15 Aug 2020 20:45:19



**US3272169**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:45:19

**US3272169**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:52:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:45:19

**US3272169**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:45:19

**US3272169**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:52:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:45:19

**US3272169**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'Jan 1994'	System	15 Aug 2020 20:45:19

**US3272169**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '1994'	System	15 Aug 2020 20:45:19

**US3272169**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 20:45:19

**US3272169**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 20:45:19



US3272169

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:52:38

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: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 20:47:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 20:47:17
Data point term sent to Coder	System	15 Aug 2020 20:46:17
User entered 'allergy to codeine'	(b) (4), (b) (6)	15 Aug 2020 20:45:33

**US3272169**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'un UNK 1990'	(b) (4), (b) (6)	15 Aug 2020 20:45:33

**US3272169**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:45:33

**US3272169**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:52:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:45:33

**US3272169**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:45:33

**US3272169**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:52:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:45:33

**US3272169**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	15 Aug 2020 20:45:33

**US3272169**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '1990'	System	15 Aug 2020 20:45:33



**US3272169**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 20:45:33

**US3272169**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 20:45:33

US3272169

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:52:38

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: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 20:47:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 20:47:17
Data point term sent to Coder	System	15 Aug 2020 20:46:19
User entered 'allergy to morphine'	(b) (4), (b) (6) (b) (4)	15 Aug 2020 20:45:52

**US3272169**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'un UNK 2007'	(b) (4), (b) (6)	15 Aug 2020 20:45:52

**US3272169**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:45:52

**US3272169**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:52:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:45:52

**US3272169**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:45:52

**US3272169**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:52:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:45:52



**US3272169**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	15 Aug 2020 20:45:52

**US3272169**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '2007'	System	15 Aug 2020 20:45:52

**US3272169**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 20:45:52

**US3272169**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 20:45:52

US3272169

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:52:38

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: Iodine allergy, LLT: Iodine allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 20:47:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 20:47:17
Data point term sent to Coder	System	15 Aug 2020 20:46:17
User entered 'allergy to iodine'	(b) (4), (b) (6) (b) (4)	15 Aug 2020 20:46:08

**US3272169**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'un UNK 1994'	(b) (4), (b) (6)	15 Aug 2020 20:46:08

**US3272169**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:46:08

**US3272169**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:52:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:46:08



**US3272169**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:46:08

**US3272169**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:52:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:46:08

**US3272169**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'Jan 1994'	System	15 Aug 2020 20:46:08

**US3272169**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '1994'	System	15 Aug 2020 20:46:08

**US3272169**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 20:46:08

**US3272169**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 20:46:08

US3272169

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:52:38

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: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 13:44:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 13:44:36
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 20:48:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 20:48:17
Data point term sent to Coder	System	15 Aug 2020 20:47:19
User entered 'allergy to toradol'	(b) (4), (b) (6) (b) (4)	15 Aug 2020 20:46:20

**US3272169**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'un UNK 1999'	(b) (4), (b) (6)	15 Aug 2020 20:46:20



**US3272169**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:46:20

**US3272169**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:52:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:46:20

**US3272169**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:46:20

**US3272169**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:52:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:46:20

**US3272169**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'Jan 1999'	System	15 Aug 2020 20:46:20

**US3272169**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '1999'	System	15 Aug 2020 20:46:20

**US3272169**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 20:46:20

**US3272169**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 20:46:20



US3272169

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:52:38

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: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 11:29:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 11:29:35
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 21:09:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 21:09:41
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 20:48:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 20:48:17
Data point term sent to Coder	System	15 Aug 2020 20:47:20
User entered 'allergy to dilaudid'	(b) (4), (b) (6) (b) (4)	15 Aug 2020 20:46:41

**US3272169**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	(b) (4), (b) (6)	15 Aug 2020 20:46:41

**US3272169**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:46:41

**US3272169**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:52:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:46:41

**US3272169**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:46:41

**US3272169**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:52:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:46:41

**US3272169**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	15 Aug 2020 20:46:41

**US3272169**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '2019'	System	15 Aug 2020 20:46:41



**US3272169**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 20:46:41

**US3272169**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 20:46:41

US3272169

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:52:38

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal fusion surgery, LLT: Spinal fusion - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 13:01:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 13:01:50
User closed query 'Per DM CLR: Please specify the specific location of Fusion 3-7 (ex. Cervical, Lumbar, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:21:26
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 13:25:06
Data point term sent to Coder	System	22 Sep 2020 00:24:33
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'is in mh as neuropathy in neck' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 00:24:29
Query 'Per DM CLR: Please specify the specific location of Fusion 3-7 (ex. Cervical, Lumbar, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 00:23:55
User entered 'ANTERIOR FUSION 3-7 PSEUDOARTHROSIS (c4-c7)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 00:23:44
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 11:13:47

US3272169

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:52:38

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please specify the specific location of Fusion 3-7 (ex. Cervical, Lumbar, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 11:13:34
Data point term sent to Coder	System	11 Sep 2020 21:28:01
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	System	11 Sep 2020 21:27:37
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' answered with 'this is one procedure' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 21:27:37
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	Coder Import (b) (4)	17 Aug 2020 16:49:07
Data point term sent to Coder	System	15 Aug 2020 20:47:21
User entered 'anterior fusion 3-7 pseudoarthrosis'	(b) (4), (b) (6)	15 Aug 2020 20:47:18

**US3272169**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'un UNK 2014'	(b) (4), (b) (6)	15 Aug 2020 20:47:18

**US3272169**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:47:18

**US3272169**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:52:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:47:18

**US3272169**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'un UNK 2014'	(b) (4), (b) (6)	15 Aug 2020 20:47:18



**US3272169**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:52:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:47:18

**US3272169**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	15 Aug 2020 20:47:18

**US3272169**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '2014'	System	15 Aug 2020 20:47:18

**US3272169**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	15 Aug 2020 20:47:18

**US3272169**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '2014'	System	15 Aug 2020 20:47:18

US3272169

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:52:38

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 13:25:07
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'fusion is listed in mh' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 00:26:26
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 11:14:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Bone therapeutic procedures NEC, PT: Bone graft, LLT: Bone graft - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 23:46:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 23:46:20
Data point term sent to Coder	System	15 Aug 2020 20:48:21
User entered 'left hip graft'	(b) (4), (b) (6)	15 Aug 2020 20:47:32

**US3272169**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'un UNK 2016'	(b) (4), (b) (6)	15 Aug 2020 20:47:32

**US3272169**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:47:32



**US3272169**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 10:52:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:47:32

**US3272169**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'un UNK 2016'	(b) (4), (b) (6)	15 Aug 2020 20:47:32

**US3272169**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 10:52:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:47:32

**US3272169**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	15 Aug 2020 20:47:32

**US3272169**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '2016'	System	15 Aug 2020 20:47:32

**US3272169**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	15 Aug 2020 20:47:32

**US3272169**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '2016'	System	15 Aug 2020 20:47:32

US3272169

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 10:52:38

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataract (left) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 17:27:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 17:27:44
Data point term sent to Coder	System	14 Oct 2020 17:26:33
User entered 'Cataract (Left eye)'	(b) (4), (b) (6)	14 Oct 2020 17:25:33



**US3272169**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'UN UNK 2013'	(b) (4), (b) (6)	14 Oct 2020 17:25:33

**US3272169**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 17:25:33

**US3272169**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 26 Nov 2020 10:52:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 17:25:33

**US3272169**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'UN May 2014'	(b) (4), (b) (6)	14 Oct 2020 17:25:33

**US3272169**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 26 Nov 2020 10:52:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 17:25:33

**US3272169**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	14 Oct 2020 17:25:33

**US3272169**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '2013'	System	14 Oct 2020 17:25:33

**US3272169**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'May 2014'	System	14 Oct 2020 17:25:33



**US3272169**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '2014'	System	14 Oct 2020 17:25:33

US3272169

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:52:38

Condition

Audit	User	Time (GMT)
User opened query 'CDM Coding: Thank you for the response. Please update the reported term as VITREOUS HUMOR (LEFT EYE)-DETAILS UNKNOWN to enable coding.' (Site from System).	Coder Import (b) (4)	24 Nov 2020 09:59:06
Data point term sent to Coder	System	23 Nov 2020 22:47:19
User closed query 'CDM-Coding: Please clarify this clinical event with more details if it is 1. Vitreous degeneration Or Something else and amend /update the term accordingly in the diagnosis field to enable coding.	System	23 Nov 2020 22:47:08
' (Site from System).		
Query 'CDM-Coding: Please clarify this clinical event with more details if it is 1. Vitreous degeneration Or Something else and amend /update the term accordingly in the diagnosis field to enable coding.	(b) (4), (b) (6)	23 Nov 2020 22:47:08
' answered with 'subject does not know any other info on med history' (Site from System).		
User opened query 'CDM-Coding: Please clarify this clinical event with more details if it is 1. Vitreous degeneration Or Something else and amend /update the term accordingly in the diagnosis field to enable coding.	Coder Import (b) (4)	23 Nov 2020 10:47:08
' (Site from System).		
Data point term sent to Coder	System	20 Nov 2020 21:56:29
User closed query 'Per CDM Coding: Please update the term with further information for a more specific meaning/diagnosis (symptom/condition). ' (Site from System).	System	20 Nov 2020 21:56:13
Query 'Per CDM Coding: Please update the term with further information for a more specific meaning/diagnosis (symptom/condition). ' answered with 'information listed is all patient knows as this condition has been resolved' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 21:56:13
User opened query 'Per CDM Coding: Please update the term with further information for a more specific meaning/diagnosis (symptom/condition). ' (Site from System).	Coder Import (b) (4)	16 Nov 2020 09:25:40
Data point term sent to Coder	System	20 Oct 2020 22:44:41

US3272169

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:52:38

[Condition](#)

Audit	User	Time (GMT)
User closed query 'DM-Coding: The verbatim term appears to be incomplete. Please update the condition/event being reported, alternatively provide more information. ' (Site from System).	System	20 Oct 2020 22:44:19
Query 'DM-Coding: The verbatim term appears to be incomplete. Please update the condition/event being reported, alternatively provide more information. ' answered with 'data is correct' (Site from System).	Kayla Flege (b) (4) (b) (4)	20 Oct 2020 22:44:19
User opened query 'DM-Coding: The verbatim term appears to be incomplete. Please update the condition/event being reported, alternatively provide more information. ' (Site from System).	Coder Import (b) (4) (b) (4)	15 Oct 2020 05:41:18
Data point term sent to Coder	System	14 Oct 2020 17:26:33
User entered 'Vitreous humor (left eye)'	(b) (4), (b) (6) (b) (4), (b) (6)	14 Oct 2020 17:26:17

**US3272169**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'UN May 2020'	(b) (4), (b) (6)	14 Oct 2020 17:26:17

**US3272169**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 17:26:17

**US3272169**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 26 Nov 2020 10:52:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 17:26:17

**US3272169**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '8 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 17:26:17

**US3272169**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 26 Nov 2020 10:52:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 17:26:17



**US3272169**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'May 2020'	System	14 Oct 2020 17:26:17

**US3272169**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '2020'	System	14 Oct 2020 17:26:17

**US3272169**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'Oct 2020'	System	14 Oct 2020 17:26:17

**US3272169**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '2020'	System	14 Oct 2020 17:26:17

US3272169

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 08:23:49
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	25 Sep 2020 22:19:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 22:19:01
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:09:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:12:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:40:40

**US3272169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Aug 2020' reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 22:19:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:12:48
User entered '15 Aug 2020'	(b) (4), (b) (6)	15 Aug 2020 20:40:40

**US3272169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '13:55' reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 22:19:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:12:48
User entered '13:55'	(b) (4), (b) (6)	15 Aug 2020 20:40:40

**US3272169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '15 Aug 2020 13:55'	System	25 Sep 2020 22:19:01
User entered empty.	System	16 Sep 2020 16:12:48
User entered '15 Aug 2020 13:55'	System	15 Aug 2020 20:40:40



US3272169

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:38

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

Audit	User	Time (GMT)
User entered '173.5' cm reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 22:19:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:12:48
User entered '173.5' cm	(b) (4), (b) (6)	15 Aug 2020 20:40:40
DataPoint set to visible.	System	15 Aug 2020 20:07:17

US3272169

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:38

Weight (xxx.x)

Audit	User	Time (GMT)
User entered '59.7' kg reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 22:19:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:12:48
User entered '59.7' kg	(b) (4), (b) (6)	15 Aug 2020 20:40:40
DataPoint set to visible.	System	15 Aug 2020 20:07:17

**US3272169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

**BMI (xxx.x)**

Audit	User	Time (GMT)
User entered '19.83240'	System	25 Sep 2020 22:19:01
User entered empty.	System	16 Sep 2020 16:12:48
User entered '19.8'	System	15 Aug 2020 20:40:40
DataPoint set to visible.	System	15 Aug 2020 20:07:17

**US3272169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	25 Sep 2020 22:19:01
User entered empty.	System	16 Sep 2020 16:12:48
User entered 'kg/m2'	System	15 Aug 2020 20:40:40
DataPoint set to visible.	System	15 Aug 2020 20:07:17

US3272169

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM Re-Query: Site response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please enter "ND" as instructed. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 08:23:51
Query 'Per CDM Re-Query: Site response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please enter "ND" as instructed. ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	25 Sep 2020 22:19:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 22:19:01
User opened query 'Per CDM Re-Query: Site response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please enter "ND" as instructed. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:09:20
User closed query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:09:20
Query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 16:12:53
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:12:48
User opened query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 21:15:44
User entered '37' C	(b) (4), (b) (6)	15 Aug 2020 20:40:40

**US3272169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:12:48
User entered 'Oral (Oral)'	(b) (4), (b) (6)	15 Aug 2020 20:40:40

**US3272169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:40:40

**US3272169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 22:19:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:12:48
User entered '69'	(b) (4), (b) (6)	15 Aug 2020 20:40:40



**US3272169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	25 Sep 2020 22:19:01
User entered empty.	System	16 Sep 2020 16:12:48
User entered 'bpm'	System	15 Aug 2020 20:40:40

**US3272169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 22:19:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:12:48
User entered '16'	(b) (4), (b) (6)	15 Aug 2020 20:40:40

**US3272169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	25 Sep 2020 22:19:01
User entered empty.	System	16 Sep 2020 16:12:48
User entered 'breaths/min'	System	15 Aug 2020 20:40:40

**US3272169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 22:19:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:12:48
User entered '119'	(b) (4), (b) (6)	15 Aug 2020 20:40:40

**US3272169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Sep 2020 22:19:01
User entered empty.	System	16 Sep 2020 16:12:48
User entered 'mmHg'	System	15 Aug 2020 20:40:40

**US3272169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 22:19:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:12:48
User entered '87'	(b) (4), (b) (6)	15 Aug 2020 20:40:40

**US3272169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Sep 2020 22:19:01
User entered empty.	System	16 Sep 2020 16:12:48
User entered 'mmHg'	System	15 Aug 2020 20:40:40

**US3272169**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 10:52:38**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 18:28:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:40:06



US3272169

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	16 Sep 2020 18:28:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 18:28:47
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	16 Sep 2020 17:49:58
User entered '15 Aug 2020'	(b) (4), (b) (6)	15 Aug 2020 20:40:06

**US3272169**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 10:52:38**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Aug 2020'	(b) (4), (b) (6)	15 Aug 2020 20:39:55

**US3272169**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 10:52:38**

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:39:55

**US3272169**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4), (b) (6)	15 Aug 2020 20:39:55

**US3272169**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 10:52:38**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:39:55

**US3272169**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'un UNK 1999'	(b) (4), (b) (6)	15 Aug 2020 20:39:55

**US3272169**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 10:52:38**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:39:55

**US3272169**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:39:55



**US3272169**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 10:52:38**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:39:55

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:38

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:38:59

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:38

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:38:59

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:38

**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 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:38:59

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:38

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:38:59

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:38

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:38:59

**US3272169**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:38:59

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:38

**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)'	(b) (4), (b) (6)	15 Aug 2020 20:38:59



**US3272169**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 10:52:38**

**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)'	(b) (4), (b) (6)	15 Aug 2020 20:38:59

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:38

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:38:59

**US3272169**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 10:52:38**

**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)'	(b) (4), (b) (6)	15 Aug 2020 20:38:59

**US3272169**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 10:52:38**

**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)'	(b) (4), (b) (6)	15 Aug 2020 20:38:59

**US3272169**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 10:52:38**

**Other**

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:38:59

**US3272169**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 10:52:38**

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:38:59

**US3272169**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 10:52:38**

**No Risk Identified**

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:38:59

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:38

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:38:59



**US3272169**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 10:52:38**

**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'	(b) (4), (b) (6)	15 Aug 2020 20:38:59

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:38

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:38:59

US3272169

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:38

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'	(b) (4), (b) (6)	15 Aug 2020 20:38:59

**US3272169**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 10:52:38**

**Resides in a single family home** (i.e., detached housing)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	15 Aug 2020 20:38:59

**US3272169**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 10:52:38**

**Other**

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:38:59

**US3272169**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 10:52:38**

**[Specify](#)**

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:38:59

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:52:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:57:44

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '15 Aug 2020'	(b) (4), (b) (6)	15 Aug 2020 20:57:44



**US3272169**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	15 Aug 2020 20:57:44

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:52:38**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	15 Aug 2020 20:57:44

US3272169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:52:38

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

Audit	User	Time (GMT)
User entered '15 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	15 Aug 2020 19:29:20

US3272169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:52:38

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:52:24
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:52:24
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	15 Aug 2020 19:29:20
User entered '104796' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	15 Aug 2020 19:29:20

US3272169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:52:38

[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]	15 Aug 2020 19:29:20

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 10:52:38**

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)'	(b) (4), (b) (6)	15 Aug 2020 20:58:02

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:58:02

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:58:02



**US3272169**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 10:52:38**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:58:02

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 10:52:38**

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:58:02

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:22:10
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:31:55

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:52:38

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:19:59
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 16:04:51
Query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	04 Sep 2020 00:22:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	04 Sep 2020 00:22:45
User opened query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:48:57
User entered '173.5' cm	(b) (4), (b) (6)	15 Aug 2020 20:59:43

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:52:38

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 16:04:51
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	04 Sep 2020 00:22:45
User entered '59.7' kg	(b) (4), (b) (6)	15 Aug 2020 20:59:43

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:52:38

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:19:59
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 16:04:51
Query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	04 Sep 2020 00:22:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	04 Sep 2020 00:22:45
User opened query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:48:57
User entered '173.5' cm	(b) (4), (b) (6)	15 Aug 2020 20:59:43

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 26 Nov 2020 10:52:38**

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 16:04:51
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	04 Sep 2020 00:22:45
User entered '59.7' kg	(b) (4), (b) (6)	15 Aug 2020 20:59:43

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:38

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	15 Aug 2020 20:59:43



**US3272169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:59:43

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:52:38**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Aug 2020'	(b) (4), (b) (6)	15 Aug 2020 20:59:43

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '13:55'	(b) (4), (b) (6)	15 Aug 2020 20:59:43

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '15 Aug 2020 13:55'	System	15 Aug 2020 20:59:43

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '37' C	(b) (4), (b) (6)	15 Aug 2020 20:59:43

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	15 Aug 2020 20:59:43

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:52:38**

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:59:43

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '69'	(b) (4), (b) (6)	15 Aug 2020 20:59:43



**US3272169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Aug 2020 20:59:43

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:38

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	15 Aug 2020 20:59:43

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	15 Aug 2020 20:59:43

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '119'	(b) (4), (b) (6)	15 Aug 2020 20:59:43

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Aug 2020 20:59:43

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '87'	(b) (4), (b) (6)	15 Aug 2020 20:59:43

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Aug 2020 20:59:43

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:52:38

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:19:59
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 16:04:51
Query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	04 Sep 2020 00:22:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	04 Sep 2020 00:22:45
User opened query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:48:57
User entered '173.5' cm	(b) (4), (b) (6)	15 Aug 2020 20:59:43



US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:52:38

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 16:04:51
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	04 Sep 2020 00:22:45
User entered '59.7' kg	(b) (4), (b) (6)	15 Aug 2020 20:59:43

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	15 Aug 2020 20:59:43

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:59:43

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:52:38**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Aug 2020'	(b) (4), (b) (6)	15 Aug 2020 20:59:43

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:38

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

Audit	User	Time (GMT)
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	18 Aug 2020 22:07:15
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		15 Aug 2020 20:59:43
User entered '15:22'	(b) (4), (b) (6)	15 Aug 2020 20:59:43

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '15 Aug 2020 15:22'	System	15 Aug 2020 20:59:43

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Sep 2020 21:24:16
Query 'Data is required. Please provide.' answered by System data change (Site from System).		11 Sep 2020 21:24:16
User entered '36.5' C reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 21:24:16
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Aug 2020 20:59:43
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:59:43

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Sep 2020 21:24:16
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 21:24:16
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Aug 2020 20:59:43
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:59:43



**US3272169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:52:38**

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'temporal' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 21:24:16
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:59:43

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '64'	(b) (4), (b) (6)	15 Aug 2020 20:59:43

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Aug 2020 20:59:43

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:38

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	15 Aug 2020 20:59:43

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	15 Aug 2020 20:59:43

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '111'	(b) (4), (b) (6)	15 Aug 2020 20:59:43

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Aug 2020 20:59:43

US3272169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '80'	(b) (4), (b) (6)	15 Aug 2020 20:59:43



**US3272169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Aug 2020 20:59:43

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 10:52:38**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:59:55

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 10:52:38**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User entered '15 Aug 2020'	(b) (4), (b) (6)	15 Aug 2020 20:59:55

US3272169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:52:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	15 Aug 2020 20:07:42

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:52:38**

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	15 Aug 2020 20:07:42

US3272169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:52:38

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

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	15 Aug 2020 20:07:42

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:52:38**

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	15 Aug 2020 20:07:42

US3272169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:52:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '15 Aug 2020'	Kayla Flege (b) (4) (b) (4)	15 Aug 2020 20:07:42



US3272169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:52:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:52'	Kayla Flege (b) (4) (b) (4)	15 Aug 2020 20:07:42

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:52:38**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 14:52'	System	15 Aug 2020 20:07:42

US3272169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:52:38

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Kayla Flege (b) (4) (b) (4)	15 Aug 2020 20:07:42

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:52:38**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:52:38**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:52:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 21:00:22

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:52:38**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Aug 2020'	(b) (4), (b) (6)	15 Aug 2020 21:00:22

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:52:38**

**Collection time (00:00-23:59)**

Audit	User	Time (GMT)
User entered '14:15'	(b) (4), (b) (6)	15 Aug 2020 21:00:22



**US3272169**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '15 Aug 2020 14:15'	System	15 Aug 2020 21:00:22

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 26 Nov 2020 10:52:38**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Aug 2020'	(b) (4), (b) (6)	15 Aug 2020 21:00:43

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	15 Aug 2020 21:00:43

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 21:00:43

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:52:38**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
User entered '14:04'	(b) (4), (b) (6)	15 Aug 2020 21:00:43

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered '15 Aug 2020 14:04'	System	15 Aug 2020 21:00:43

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	15 Aug 2020 21:00:43

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 21:00:43



US3272169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:52:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 21:00:43

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 21:00:43

US3272169

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:52:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Aug 2020 21:01:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Aug 2020 21:01:05
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Aug 2020 21:01:05
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Aug 2020 21:00:52
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 21:00:52

**US3272169**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:52:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 21:01:05
User entered empty.	System	15 Aug 2020 21:00:52

**US3272169**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Aug 2020 20:07:42

**US3272169**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:15:50', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '32185203-914c-4fad-bfc7-dc6bc2d0f2cc'	System	15 Aug 2020 20:16:16
User entered 'Yes (Y)'	System	15 Aug 2020 20:16:16

**US3272169**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:15:56', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '32185203-914c-4fad-bfc7-dc6bc2d0f2cc'	System	15 Aug 2020 20:16:16
User entered '98.4'	System	15 Aug 2020 20:16:16

**US3272169**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:16:04', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '32185203-914c-4fad-bfc7-dc6bc2d0f2cc'	System	15 Aug 2020 20:16:16
User entered 'No (N)'	System	15 Aug 2020 20:16:16



**US3272169**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:16:12', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '32185203-914c-4fad-bfc7-dc6bc2d0f2cc'	System	15 Aug 2020 20:16:16
User entered '15 Aug 2020 15:16'	System	15 Aug 2020 20:16:16

**US3272169**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 15:12'	System	15 Aug 2020 20:07:42

**US3272169**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 17:42'	System	15 Aug 2020 20:07:42

**US3272169**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered 'Day 1, after vaccination (at home)'	System	15 Aug 2020 20:07:42

**US3272169**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:03:24', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '84b185da-b754-4989-93c6-a12726b08092'	System	16 Aug 2020 02:03:45
User entered 'Yes (Y)'	System	16 Aug 2020 02:03:45

**US3272169**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:03:30', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '84b185da-b754-4989-93c6-a12726b08092'	System	16 Aug 2020 02:03:45
User entered '98.7'	System	16 Aug 2020 02:03:45

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:52:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:03:34', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '84b185da-b754-4989-93c6-a12726b08092'	System	16 Aug 2020 02:03:45
User entered 'No (N)'	System	16 Aug 2020 02:03:45

**US3272169**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:03:43', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '84b185da-b754-4989-93c6-a12726b08092'	System	16 Aug 2020 02:03:45
User entered '15 Aug 2020 21:03'	System	16 Aug 2020 02:03:45



**US3272169**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 18:37'	System	15 Aug 2020 20:07:42

**US3272169**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	15 Aug 2020 20:07:42

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered 'Day 2'	System	15 Aug 2020 20:07:42

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:55:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5c9c10b2-aca9-4bea-8f24-f2d634da95f9'	System	16 Aug 2020 20:56:14
User entered 'No (N)'	System	16 Aug 2020 20:56:14

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:52:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:55:52', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5c9c10b2-aca9-4bea-8f24-f2d634da95f9'	System	16 Aug 2020 20:56:14
User entered 'Yes (Y)'	System	16 Aug 2020 20:56:14

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:52:38

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 'updated con med log' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 13:38:02
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 (e45941109fd6dbd5)', Time: '2020-08-16T15:56:01', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5c9c10b2-aca9-4bea-8f24-f2d634da95f9'	System	16 Aug 2020 20:56:14
User entered '1'	System	16 Aug 2020 20:56:14

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:56:01', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5c9c10b2-aca9-4bea-8f24-f2d634da95f9'	System	16 Aug 2020 20:56:14
User entered '0'	System	16 Aug 2020 20:56:14

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:56:13', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5c9c10b2-aca9-4bea-8f24-f2d634da95f9'	System	16 Aug 2020 20:56:14
User entered '16 Aug 2020 15:56'	System	16 Aug 2020 20:56:14



**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	15 Aug 2020 20:07:42

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	15 Aug 2020 20:07:42

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered 'Day 3'	System	15 Aug 2020 20:07:42

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:49:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd505c133-07ff-406f-aaad-8e63dd83ae06'	System	18 Aug 2020 02:50:15
User entered 'Yes (Y)'	System	18 Aug 2020 02:50:15

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:49:55', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd505c133-07ff-406f-aaad-8e63dd83ae06'	System	18 Aug 2020 02:50:15
User entered '98.6'	System	18 Aug 2020 02:50:15

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:50:02', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd505c133-07ff-406f-aaad-8e63dd83ae06'	System	18 Aug 2020 02:50:15
User entered 'Yes (Y)'	System	18 Aug 2020 02:50:15

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:52:38

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 'updated con med log' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 13:38:12
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 (e45941109fd6dbd5)', Time: '2020-08-17T21:50:08', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd505c133-07ff-406f-aaad-8e63dd83ae06'	System	18 Aug 2020 02:50:15
User entered '1'	System	18 Aug 2020 02:50:15

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:50:08', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd505c133-07ff-406f-aaad-8e63dd83ae06'	System	18 Aug 2020 02:50:15
User entered '0'	System	18 Aug 2020 02:50:15



**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:50:14', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd505c133-07ff-406f-aaad-8e63dd83ae06'	System	18 Aug 2020 02:50:15
User entered '17 Aug 2020 21:50'	System	18 Aug 2020 02:50:15

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	15 Aug 2020 20:07:42

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	15 Aug 2020 20:07:42

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered 'Day 4'	System	15 Aug 2020 20:07:42

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:41:41', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '67d08138-2bcd-4da2-af87-2f8dd1d0e902'	System	19 Aug 2020 04:41:59
User entered 'Yes (Y)'	System	19 Aug 2020 04:41:59

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:41:47', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '67d08138-2bcd-4da2-af87-2f8dd1d0e902'	System	19 Aug 2020 04:41:59
User entered '97.0'	System	19 Aug 2020 04:41:59

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:41:50', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '67d08138-2bcd-4da2-af87-2f8dd1d0e902'	System	19 Aug 2020 04:41:59
User entered 'No (N)'	System	19 Aug 2020 04:41:59

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:41:57', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '67d08138-2bcd-4da2-af87-2f8dd1d0e902'	System	19 Aug 2020 04:41:59
User entered '18 Aug 2020 23:41'	System	19 Aug 2020 04:41:59



**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	15 Aug 2020 20:07:42

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	15 Aug 2020 20:07:42

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered 'Day 5'	System	15 Aug 2020 20:07:42

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:13:47', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c727d694-2338-4230-bee8-a96d83c6c832'	System	20 Aug 2020 03:14:04
User entered 'Yes (Y)'	System	20 Aug 2020 03:14:04

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:13:53', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c727d694-2338-4230-bee8-a96d83c6c832'	System	20 Aug 2020 03:14:04
User entered '98.2'	System	20 Aug 2020 03:14:04

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:13:56', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c727d694-2338-4230-bee8-a96d83c6c832'	System	20 Aug 2020 03:14:04
User entered 'No (N)'	System	20 Aug 2020 03:14:04

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:14:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c727d694-2338-4230-bee8-a96d83c6c832'	System	20 Aug 2020 03:14:04
User entered '19 Aug 2020 22:14'	System	20 Aug 2020 03:14:04

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	15 Aug 2020 20:07:42



**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	15 Aug 2020 20:07:42

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered 'Day 6'	System	15 Aug 2020 20:07:42

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:37:57', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '87a6faf8-c5a2-41e6-bc38-61fb5887934f'	System	21 Aug 2020 02:38:13
User entered 'Yes (Y)'	System	21 Aug 2020 02:38:13

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:38:02', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '87a6faf8-c5a2-41e6-bc38-61fb5887934f'	System	21 Aug 2020 02:38:13
User entered '98.0'	System	21 Aug 2020 02:38:13

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:38:05', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '87a6faf8-c5a2-41e6-bc38-61fb5887934f'	System	21 Aug 2020 02:38:13
User entered 'No (N)'	System	21 Aug 2020 02:38:13

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:38:11', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '87a6faf8-c5a2-41e6-bc38-61fb5887934f'	System	21 Aug 2020 02:38:13
User entered '20 Aug 2020 21:38'	System	21 Aug 2020 02:38:13

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	15 Aug 2020 20:07:42

**US3272169**

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

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

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	15 Aug 2020 20:07:42



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered 'Day 7'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:04:33', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b1f75a43-588b-4516-92ea-e83c8b0b9e47'	System	22 Aug 2020 05:04:53
User entered 'Yes (Y)'	System	22 Aug 2020 05:04:53

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:04:38', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b1f75a43-588b-4516-92ea-e83c8b0b9e47'	System	22 Aug 2020 05:04:53
User entered '99.9'	System	22 Aug 2020 05:04:53

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:52:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:04:42', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b1f75a43-588b-4516-92ea-e83c8b0b9e47'	System	22 Aug 2020 05:04:53
User entered 'Yes (Y)'	System	22 Aug 2020 05:04:53

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:52:38

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 'updated con med log' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 13:38:26
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 (e45941109fd6dbd5)', Time: '2020-08-22T00:04:46', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b1f75a43-588b-4516-92ea-e83c8b0b9e47'	System	22 Aug 2020 05:04:53
User entered '1'	System	22 Aug 2020 05:04:53

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:04:46', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b1f75a43-588b-4516-92ea-e83c8b0b9e47'	System	22 Aug 2020 05:04:53
User entered '0'	System	22 Aug 2020 05:04:53

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:04:50', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b1f75a43-588b-4516-92ea-e83c8b0b9e47'	System	22 Aug 2020 05:04:53
User entered '22 Aug 2020 00:04'	System	22 Aug 2020 05:04:53

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	15 Aug 2020 20:07:42



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	22 Aug 2020 05:04:53
User entered 'Day 8'	System	22 Aug 2020 05:04:53

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T21:46:17', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a39e57bb-5bd0-43da-839c-2540f423aeb0'	System	23 Aug 2020 02:46:41
User entered 'Yes (Y)'	System	23 Aug 2020 02:46:41

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T21:46:22', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a39e57bb-5bd0-43da-839c-2540f423aeb0'	System	23 Aug 2020 02:46:41
User entered '98.9'	System	23 Aug 2020 02:46:41

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

**Was any MEDICATION TAKEN today for pain or fever?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T21:46:28', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a39e57bb-5bd0-43da-839c-2540f423aeb0'	System	23 Aug 2020 02:46:41
User entered 'Yes (Y)'	System	23 Aug 2020 02:46:41

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 26 Nov 2020 10:52:38

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 'updated con med log' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 13:38:37
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 (e45941109fd6dbd5)', Time: '2020-08-22T21:46:33', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a39e57bb-5bd0-43da-839c-2540f423aeb0'	System	23 Aug 2020 02:46:41
User entered '1'	System	23 Aug 2020 02:46:41

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T21:46:33', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a39e57bb-5bd0-43da-839c-2540f423aeb0' User entered '0'	System	23 Aug 2020 02:46:41

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T21:46:37', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a39e57bb-5bd0-43da-839c-2540f423aeb0'	System	23 Aug 2020 02:46:41
User entered '22 Aug 2020 21:46'	System	23 Aug 2020 02:46:41



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	22 Aug 2020 05:04:53

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 05:04:53

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	22 Aug 2020 05:04:53
User entered 'Day 9'	System	22 Aug 2020 05:04:53

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-23T23:42:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '3467424d-7be3-4cfe-89ee-81d72fc2106e'	System	24 Aug 2020 04:42:19
User entered 'Yes (Y)'	System	24 Aug 2020 04:42:19

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-23T23:42:05', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '3467424d-7be3-4cfe-89ee-81d72fc2106e'	System	24 Aug 2020 04:42:19
User entered '98.9'	System	24 Aug 2020 04:42:19

US3272169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 26 Nov 2020 10:52:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-23T23:42:12', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '3467424d-7be3-4cfe-89ee-81d72fc2106e'	System	24 Aug 2020 04:42:19
User entered 'No (N)'	System	24 Aug 2020 04:42:19

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-23T23:42:17', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '3467424d-7be3-4cfe-89ee-81d72fc2106e'	System	24 Aug 2020 04:42:19
User entered '23 Aug 2020 23:42'	System	24 Aug 2020 04:42:19

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 05:04:53



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 05:04:53

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-08-15T15:16:30', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd0fd5289-b3bb-4c4d-8aaa-695a6670ddfc'	System	15 Aug 2020 20:17:07
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 20:17:07

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:16:43', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd0fd5289-b3bb-4c4d-8aaa-695a6670ddfc'	System	15 Aug 2020 20:17:07
User entered 'No (N)'	System	15 Aug 2020 20:17:07

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:16:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd0fd5289-b3bb-4c4d-8aaa-695a6670ddfc'	System	15 Aug 2020 20:17:07
User entered 'No (N)'	System	15 Aug 2020 20:17:07

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-08-15T15:16:59', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd0fd5289-b3bb-4c4d-8aaa-695a6670ddfc'	System	15 Aug 2020 20:17:07
User entered 'None (1)'	System	15 Aug 2020 20:17:07

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:17:06', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd0fd5289-b3bb-4c4d-8aaa-695a6670ddfc'	System	15 Aug 2020 20:17:07
User entered '15 Aug 2020 15:17'	System	15 Aug 2020 20:17:07

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 15:12'	System	15 Aug 2020 20:07:42



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 17:42'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered 'Day 1, after vaccination (at home)'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-08-15T21:04:41', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b49ca638-8c46-4ff1-8b27-3a9cb3471f25'	System	16 Aug 2020 02:05:19
User entered 'Does not interfere with activity (2)'	System	16 Aug 2020 02:05:19

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:04:44', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b49ca638-8c46-4ff1-8b27-3a9cb3471f25'	System	16 Aug 2020 02:05:19
User entered 'No (N)'	System	16 Aug 2020 02:05:19

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:04:52', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b49ca638-8c46-4ff1-8b27-3a9cb3471f25'	System	16 Aug 2020 02:05:19
User entered 'No (N)'	System	16 Aug 2020 02:05:19

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-08-15T21:05:08', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b49ca638-8c46-4ff1-8b27-3a9cb3471f25'	System	16 Aug 2020 02:05:19
User entered 'Does not interfere with activity (2)'	System	16 Aug 2020 02:05:19

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:05:18', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b49ca638-8c46-4ff1-8b27-3a9cb3471f25'	System	16 Aug 2020 02:05:19
User entered '15 Aug 2020 21:05'	System	16 Aug 2020 02:05:19

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 18:37'	System	15 Aug 2020 20:07:42



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered 'Day 2'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-08-16T15:57:22', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c62b455a-8d84-43e2-ac9b-c7329ca10fa5'	System	16 Aug 2020 20:57:55
User entered 'Does not interfere with activity (2)'	System	16 Aug 2020 20:57:55

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:57:26', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c62b455a-8d84-43e2-ac9b-c7329ca10fa5'	System	16 Aug 2020 20:57:55
User entered 'No (N)'	System	16 Aug 2020 20:57:55

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:57:39', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c62b455a-8d84-43e2-ac9b-c7329ca10fa5'	System	16 Aug 2020 20:57:55
User entered 'No (N)'	System	16 Aug 2020 20:57:55

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-08-16T15:57:48', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c62b455a-8d84-43e2-ac9b-c7329ca10fa5'	System	16 Aug 2020 20:57:55
User entered 'None (1)'	System	16 Aug 2020 20:57:55

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:57:53', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c62b455a-8d84-43e2-ac9b-c7329ca10fa5'	System	16 Aug 2020 20:57:55
User entered '16 Aug 2020 15:57'	System	16 Aug 2020 20:57:55

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	15 Aug 2020 20:07:42



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered 'Day 3'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-08-17T21:50:23', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5a20133c-d39b-4c51-9a54-f3332219d744'	System	18 Aug 2020 02:50:41
User entered 'Does not interfere with activity (2)'	System	18 Aug 2020 02:50:41

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:50:26', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5a20133c-d39b-4c51-9a54-f3332219d744'	System	18 Aug 2020 02:50:41
User entered 'No (N)'	System	18 Aug 2020 02:50:41

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:50:33', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5a20133c-d39b-4c51-9a54-f3332219d744'	System	18 Aug 2020 02:50:41
User entered 'No (N)'	System	18 Aug 2020 02:50:41

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-08-17T21:50:36', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5a20133c-d39b-4c51-9a54-f3332219d744'	System	18 Aug 2020 02:50:41
User entered 'None (1)'	System	18 Aug 2020 02:50:41

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:50:40', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5a20133c-d39b-4c51-9a54-f3332219d744'	System	18 Aug 2020 02:50:41
User entered '17 Aug 2020 21:50'	System	18 Aug 2020 02:50:41

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	15 Aug 2020 20:07:42



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered 'Day 4'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-08-18T23:42:11', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f8767d77-a566-4a2b-aceb-f0e237e31bf4'	System	19 Aug 2020 04:42:34
User entered 'None (1)'	System	19 Aug 2020 04:42:34

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:42:14', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f8767d77-a566-4a2b-aceb-f0e237e31bf4'	System	19 Aug 2020 04:42:34
User entered 'No (N)'	System	19 Aug 2020 04:42:34

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:42:16', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f8767d77-a566-4a2b-aceb-f0e237e31bf4'	System	19 Aug 2020 04:42:34
User entered 'No (N)'	System	19 Aug 2020 04:42:34

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-08-18T23:42:27', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f8767d77-a566-4a2b-aceb-f0e237e31bf4'	System	19 Aug 2020 04:42:34
User entered 'None (1)'	System	19 Aug 2020 04:42:34

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:42:31', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f8767d77-a566-4a2b-aceb-f0e237e31bf4'	System	19 Aug 2020 04:42:34
User entered '18 Aug 2020 23:42'	System	19 Aug 2020 04:42:34

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	15 Aug 2020 20:07:42



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered 'Day 5'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-08-19T22:14:08', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '61fcb639-bc80-481e-8a49-8fe6f856357f'	System	20 Aug 2020 03:14:28
User entered 'None (1)'	System	20 Aug 2020 03:14:28

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:14:11', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '61fcb639-bc80-481e-8a49-8fe6f856357f'	System	20 Aug 2020 03:14:28
User entered 'No (N)'	System	20 Aug 2020 03:14:28

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:14:14', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '61fcb639-bc80-481e-8a49-8fe6f856357f'	System	20 Aug 2020 03:14:28
User entered 'No (N)'	System	20 Aug 2020 03:14:28

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-08-19T22:14:17', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '61fcb639-bc80-481e-8a49-8fe6f856357f'	System	20 Aug 2020 03:14:28
User entered 'None (1)'	System	20 Aug 2020 03:14:28

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:14:25', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '61fcb639-bc80-481e-8a49-8fe6f856357f'	System	20 Aug 2020 03:14:28
User entered '19 Aug 2020 22:14'	System	20 Aug 2020 03:14:28

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	15 Aug 2020 20:07:42



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered 'Day 6'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-08-20T21:38:15', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f00d3131-01bc-49b3-8966-1d7c50ccf2b7'	System	21 Aug 2020 02:38:35
User entered 'None (1)'	System	21 Aug 2020 02:38:35

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:38:20', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f00d3131-01bc-49b3-8966-1d7c50ccf2b7'	System	21 Aug 2020 02:38:35
User entered 'No (N)'	System	21 Aug 2020 02:38:35

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:38:22', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f00d3131-01bc-49b3-8966-1d7c50ccf2b7'	System	21 Aug 2020 02:38:35
User entered 'No (N)'	System	21 Aug 2020 02:38:35

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-08-20T21:38:27', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f00d3131-01bc-49b3-8966-1d7c50ccf2b7'	System	21 Aug 2020 02:38:35
User entered 'None (1)'	System	21 Aug 2020 02:38:35

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:38:31', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f00d3131-01bc-49b3-8966-1d7c50ccf2b7'	System	21 Aug 2020 02:38:35
User entered '20 Aug 2020 21:38'	System	21 Aug 2020 02:38:35

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	15 Aug 2020 20:07:42



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered 'Day 7'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-08-22T00:04:15', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4451e241-b091-49f7-91b3-3e45902ecf45'	System	22 Aug 2020 05:04:29
User entered 'None (1)'	System	22 Aug 2020 05:04:29

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:04:18', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4451e241-b091-49f7-91b3-3e45902ecf45'	System	22 Aug 2020 05:04:29
User entered 'No (N)'	System	22 Aug 2020 05:04:29

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:04:21', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4451e241-b091-49f7-91b3-3e45902ecf45'	System	22 Aug 2020 05:04:29
User entered 'No (N)'	System	22 Aug 2020 05:04:29

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-08-22T00:04:23', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4451e241-b091-49f7-91b3-3e45902ecf45'	System	22 Aug 2020 05:04:29
User entered 'None (1)'	System	22 Aug 2020 05:04:29

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:04:27', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4451e241-b091-49f7-91b3-3e45902ecf45'	System	22 Aug 2020 05:04:29
User entered '22 Aug 2020 00:04'	System	22 Aug 2020 05:04:29

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	15 Aug 2020 20:07:42



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:17:12', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd8a0f3c1-eb69-4321-b062-98a67c7e0730'	System	15 Aug 2020 20:17:53
User entered 'None (0)'	System	15 Aug 2020 20:17:53

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:17:26', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd8a0f3c1-eb69-4321-b062-98a67c7e0730'	System	15 Aug 2020 20:17:53
User entered 'None (0)'	System	15 Aug 2020 20:17:53

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:17:29', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd8a0f3c1-eb69-4321-b062-98a67c7e0730'	System	15 Aug 2020 20:17:53
User entered 'None (0)'	System	15 Aug 2020 20:17:53

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:17:32', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd8a0f3c1-eb69-4321-b062-98a67c7e0730'	System	15 Aug 2020 20:17:53
User entered 'None (0)'	System	15 Aug 2020 20:17:53

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:17:35', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd8a0f3c1-eb69-4321-b062-98a67c7e0730'	System	15 Aug 2020 20:17:53
User entered 'None (0)'	System	15 Aug 2020 20:17:53

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:17:37', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd8a0f3c1-eb69-4321-b062-98a67c7e0730'	System	15 Aug 2020 20:17:53
User entered 'None (0)'	System	15 Aug 2020 20:17:53



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-08-15T15:17:46', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd8a0f3c1-eb69-4321-b062-98a67c7e0730'	System	15 Aug 2020 20:17:53
User entered 'No (N)'	System	15 Aug 2020 20:17:53

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T15:17:51', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd8a0f3c1-eb69-4321-b062-98a67c7e0730'	System	15 Aug 2020 20:17:53
User entered '15 Aug 2020 15:17'	System	15 Aug 2020 20:17:53

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 15:12'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 17:42'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered 'Day 1, after vaccination (at home)'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:03:53', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '165eaab7-df22-4950-8b04-4724939577d9'	System	16 Aug 2020 02:04:26
User entered 'None (0)'	System	16 Aug 2020 02:04:26

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:03:57', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '165eaab7-df22-4950-8b04-4724939577d9'	System	16 Aug 2020 02:04:26
User entered 'No interference with activity (1)'	System	16 Aug 2020 02:04:26

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:04:01', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '165eaab7-df22-4950-8b04-4724939577d9'	System	16 Aug 2020 02:04:26
User entered 'None (0)'	System	16 Aug 2020 02:04:26



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:04:04', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '165eaab7-df22-4950-8b04-4724939577d9'	System	16 Aug 2020 02:04:26
User entered 'None (0)'	System	16 Aug 2020 02:04:26

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:04:07', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '165eaab7-df22-4950-8b04-4724939577d9'	System	16 Aug 2020 02:04:26
User entered 'None (0)'	System	16 Aug 2020 02:04:26

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:04:09', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '165eaab7-df22-4950-8b04-4724939577d9'	System	16 Aug 2020 02:04:26
User entered 'None (0)'	System	16 Aug 2020 02:04:26

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-08-15T21:04:16', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '165eaab7-df22-4950-8b04-4724939577d9'	System	16 Aug 2020 02:04:26
User entered 'No (N)'	System	16 Aug 2020 02:04:26

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-15T21:04:24', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '165eaab7-df22-4950-8b04-4724939577d9'	System	16 Aug 2020 02:04:26
User entered '15 Aug 2020 21:04'	System	16 Aug 2020 02:04:26

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 18:37'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered 'Day 2'	System	15 Aug 2020 20:07:42



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:56:39', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '522aa4ab-174b-4b92-8f26-fc568a66f452'	System	16 Aug 2020 20:57:14
User entered 'No interference with activity (1)'	System	16 Aug 2020 20:57:14

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:56:45', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '522aa4ab-174b-4b92-8f26-fc568a66f452'	System	16 Aug 2020 20:57:14
User entered 'No interference with activity (1)'	System	16 Aug 2020 20:57:14

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:56:48', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '522aa4ab-174b-4b92-8f26-fc568a66f452'	System	16 Aug 2020 20:57:14
User entered 'No interference with activity (1)'	System	16 Aug 2020 20:57:14

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:56:53', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '522aa4ab-174b-4b92-8f26-fc568a66f452'	System	16 Aug 2020 20:57:14
User entered 'No interference with activity (1)'	System	16 Aug 2020 20:57:14

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:56:57', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '522aa4ab-174b-4b92-8f26-fc568a66f452'	System	16 Aug 2020 20:57:14
User entered 'None (0)'	System	16 Aug 2020 20:57:14

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:57:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '522aa4ab-174b-4b92-8f26-fc568a66f452'	System	16 Aug 2020 20:57:14
User entered 'None (0)'	System	16 Aug 2020 20:57:14

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-08-16T15:57:05', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '522aa4ab-174b-4b92-8f26-fc568a66f452'	System	16 Aug 2020 20:57:14
User entered 'No (N)'	System	16 Aug 2020 20:57:14

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-16T15:57:12', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '522aa4ab-174b-4b92-8f26-fc568a66f452'	System	16 Aug 2020 20:57:14
User entered '16 Aug 2020 15:57'	System	16 Aug 2020 20:57:14



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered 'Day 3'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:50:45', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a150e56f-c53b-41eb-9446-827473cf92a7'	System	18 Aug 2020 02:51:22
User entered 'No interference with activity (1)'	System	18 Aug 2020 02:51:22

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:50:52', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a150e56f-c53b-41eb-9446-827473cf92a7'	System	18 Aug 2020 02:51:22
User entered 'No interference with activity (1)'	System	18 Aug 2020 02:51:22

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:50:57', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a150e56f-c53b-41eb-9446-827473cf92a7'	System	18 Aug 2020 02:51:22
User entered 'None (0)'	System	18 Aug 2020 02:51:22

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:51:02', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a150e56f-c53b-41eb-9446-827473cf92a7'	System	18 Aug 2020 02:51:22
User entered 'None (0)'	System	18 Aug 2020 02:51:22

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:51:09', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a150e56f-c53b-41eb-9446-827473cf92a7'	System	18 Aug 2020 02:51:22
User entered 'None (0)'	System	18 Aug 2020 02:51:22



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:51:12', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a150e56f-c53b-41eb-9446-827473cf92a7'	System	18 Aug 2020 02:51:22
User entered 'None (0)'	System	18 Aug 2020 02:51:22

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-08-17T21:51:18', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a150e56f-c53b-41eb-9446-827473cf92a7'	System	18 Aug 2020 02:51:22
User entered 'No (N)'	System	18 Aug 2020 02:51:22

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-17T21:51:21', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a150e56f-c53b-41eb-9446-827473cf92a7'	System	18 Aug 2020 02:51:22
User entered '17 Aug 2020 21:51'	System	18 Aug 2020 02:51:22

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered 'Day 4'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:42:36', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b360058b-f9cc-43f6-a7a6-27e0c7ce47a9'	System	19 Aug 2020 04:43:13
User entered 'None (0)'	System	19 Aug 2020 04:43:13

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:42:41', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b360058b-f9cc-43f6-a7a6-27e0c7ce47a9'	System	19 Aug 2020 04:43:13
User entered 'Some interference with activity (2)'	System	19 Aug 2020 04:43:13



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:42:46', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b360058b-f9cc-43f6-a7a6-27e0c7ce47a9'	System	19 Aug 2020 04:43:13
User entered 'None (0)'	System	19 Aug 2020 04:43:13

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:42:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b360058b-f9cc-43f6-a7a6-27e0c7ce47a9'	System	19 Aug 2020 04:43:13
User entered 'None (0)'	System	19 Aug 2020 04:43:13

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:42:53', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b360058b-f9cc-43f6-a7a6-27e0c7ce47a9'	System	19 Aug 2020 04:43:13
User entered 'None (0)'	System	19 Aug 2020 04:43:13

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:42:56', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b360058b-f9cc-43f6-a7a6-27e0c7ce47a9'	System	19 Aug 2020 04:43:13
User entered 'None (0)'	System	19 Aug 2020 04:43:13

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-08-18T23:43:04', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b360058b-f9cc-43f6-a7a6-27e0c7ce47a9'	System	19 Aug 2020 04:43:13
User entered 'No (N)'	System	19 Aug 2020 04:43:13

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-18T23:43:11', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b360058b-f9cc-43f6-a7a6-27e0c7ce47a9'	System	19 Aug 2020 04:43:13
User entered '18 Aug 2020 23:43'	System	19 Aug 2020 04:43:13

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	15 Aug 2020 20:07:42



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered 'Day 5'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:14:30', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4d3cfe9c-89ef-40e7-ac35-61042e2fd129'	System	20 Aug 2020 03:15:04
User entered 'None (0)'	System	20 Aug 2020 03:15:04

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:14:39', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4d3cfe9c-89ef-40e7-ac35-61042e2fd129'	System	20 Aug 2020 03:15:04
User entered 'No interference with activity (1)'	System	20 Aug 2020 03:15:04

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:14:42', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4d3cfe9c-89ef-40e7-ac35-61042e2fd129'	System	20 Aug 2020 03:15:04
User entered 'None (0)'	System	20 Aug 2020 03:15:04

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:14:45', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4d3cfe9c-89ef-40e7-ac35-61042e2fd129'	System	20 Aug 2020 03:15:04
User entered 'None (0)'	System	20 Aug 2020 03:15:04

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:14:48', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4d3cfe9c-89ef-40e7-ac35-61042e2fd129'	System	20 Aug 2020 03:15:04
User entered 'None (0)'	System	20 Aug 2020 03:15:04

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:14:50', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4d3cfe9c-89ef-40e7-ac35-61042e2fd129'	System	20 Aug 2020 03:15:04
User entered 'None (0)'	System	20 Aug 2020 03:15:04

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-08-19T22:14:55', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4d3cfe9c-89ef-40e7-ac35-61042e2fd129'	System	20 Aug 2020 03:15:04
User entered 'No (N)'	System	20 Aug 2020 03:15:04



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-19T22:14:59', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4d3cfe9c-89ef-40e7-ac35-61042e2fd129'	System	20 Aug 2020 03:15:04
User entered '19 Aug 2020 22:14'	System	20 Aug 2020 03:15:04

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered 'Day 6'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:38:35', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2d81c1e6-1a64-4a7c-8ba5-f48b20a500f6'	System	21 Aug 2020 02:39:08
User entered 'None (0)'	System	21 Aug 2020 02:39:08

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:38:39', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2d81c1e6-1a64-4a7c-8ba5-f48b20a500f6'	System	21 Aug 2020 02:39:08
User entered 'Some interference with activity (2)'	System	21 Aug 2020 02:39:08

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:38:43', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2d81c1e6-1a64-4a7c-8ba5-f48b20a500f6'	System	21 Aug 2020 02:39:08
User entered 'None (0)'	System	21 Aug 2020 02:39:08

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:38:46', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2d81c1e6-1a64-4a7c-8ba5-f48b20a500f6'	System	21 Aug 2020 02:39:08
User entered 'None (0)'	System	21 Aug 2020 02:39:08



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:38:48', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2d81c1e6-1a64-4a7c-8ba5-f48b20a500f6'	System	21 Aug 2020 02:39:08
User entered 'None (0)'	System	21 Aug 2020 02:39:08

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:38:51', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2d81c1e6-1a64-4a7c-8ba5-f48b20a500f6'	System	21 Aug 2020 02:39:08
User entered 'None (0)'	System	21 Aug 2020 02:39:08

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-08-20T21:38:56', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2d81c1e6-1a64-4a7c-8ba5-f48b20a500f6'	System	21 Aug 2020 02:39:08
User entered 'No (N)'	System	21 Aug 2020 02:39:08

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-20T21:39:04', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2d81c1e6-1a64-4a7c-8ba5-f48b20a500f6'	System	21 Aug 2020 02:39:08
User entered '20 Aug 2020 21:39'	System	21 Aug 2020 02:39:08

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered 'Day 7'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:04:55', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '525b372e-2f6a-41c0-9a02-33bb0f6313ec'	System	22 Aug 2020 05:05:15
User entered 'None (0)'	System	22 Aug 2020 05:05:15



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:04:58', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '525b372e-2f6a-41c0-9a02-33bb0f6313ec'	System	22 Aug 2020 05:05:15
User entered 'No interference with activity (1)'	System	22 Aug 2020 05:05:15

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:05:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '525b372e-2f6a-41c0-9a02-33bb0f6313ec'	System	22 Aug 2020 05:05:15
User entered 'None (0)'	System	22 Aug 2020 05:05:15

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:05:02', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '525b372e-2f6a-41c0-9a02-33bb0f6313ec'	System	22 Aug 2020 05:05:15
User entered 'None (0)'	System	22 Aug 2020 05:05:15

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:05:05', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '525b372e-2f6a-41c0-9a02-33bb0f6313ec'	System	22 Aug 2020 05:05:15
User entered 'None (0)'	System	22 Aug 2020 05:05:15

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:05:07', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '525b372e-2f6a-41c0-9a02-33bb0f6313ec'	System	22 Aug 2020 05:05:15
User entered 'None (0)'	System	22 Aug 2020 05:05:15

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-08-22T00:05:09', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '525b372e-2f6a-41c0-9a02-33bb0f6313ec'	System	22 Aug 2020 05:05:15
User entered 'No (N)'	System	22 Aug 2020 05:05:15

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T00:05:12', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '525b372e-2f6a-41c0-9a02-33bb0f6313ec'	System	22 Aug 2020 05:05:15
User entered '22 Aug 2020 00:05'	System	22 Aug 2020 05:05:15

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	15 Aug 2020 20:07:42



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 02:39:08
User entered 'Day 8'	System	21 Aug 2020 02:39:08

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-08-22T21:46:44', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '30245d40-97ce-4433-9eaf-6021f3b3d793'	System	23 Aug 2020 02:46:52
User entered 'No interference with activity (1)'	System	23 Aug 2020 02:46:52

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T21:46:51', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '30245d40-97ce-4433-9eaf-6021f3b3d793'	System	23 Aug 2020 02:46:52
User entered '22 Aug 2020 21:46'	System	23 Aug 2020 02:46:52

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 02:39:08

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 02:39:08

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	22 Aug 2020 05:05:15
User entered 'Day 9'	System	22 Aug 2020 05:05:15

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-08-23T23:42:22', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '86dcfb08-baeb-4dfe-a3e3-c78fd74958f3'	System	24 Aug 2020 04:42:30
User entered 'Some interference with activity (2)'	System	24 Aug 2020 04:42:30



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-23T23:42:25', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '86dcfb08-baeb-4dfe-a3e3-c78fd74958f3'	System	24 Aug 2020 04:42:30
User entered '23 Aug 2020 23:42'	System	24 Aug 2020 04:42:30

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 05:05:15

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 05:05:15

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Aug 2020 02:46:52
User entered 'Day 10'	System	23 Aug 2020 02:46:52

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 02:46:52

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 02:46:52

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 04:42:30
User entered 'Day 11'	System	24 Aug 2020 04:42:30

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-08-25T23:56:50', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'cc841b5a-bbfe-4bb1-b516-915f46101635'	System	26 Aug 2020 04:56:58
User entered 'No interference with activity (1)'	System	26 Aug 2020 04:56:58



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-25T23:56:54', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'cc841b5a-bbfe-4bb1-b516-915f46101635'	System	26 Aug 2020 04:56:58
User entered '25 Aug 2020 23:56'	System	26 Aug 2020 04:56:58

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 04:42:30

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 04:42:30

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 04:56:58
User entered 'Day 12'	System	26 Aug 2020 04:56:58

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	26 Aug 2020 04:56:58

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 04:56:58

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 04:56:58
User entered 'Day 13'	System	26 Aug 2020 04:56:58

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-08-28T00:30:52', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '301f67bd-b6a9-44c4-87f4-20f9c60cb09a'	System	28 Aug 2020 05:30:58
User entered 'Some interference with activity (2)'	System	28 Aug 2020 05:30:58



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-28T00:30:55', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '301f67bd-b6a9-44c4-87f4-20f9c60cb09a'	System	28 Aug 2020 05:30:58
User entered '28 Aug 2020 00:30'	System	28 Aug 2020 05:30:58

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 04:56:58

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 04:56:58

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 05:30:58
User entered 'Day 14'	System	28 Aug 2020 05:30:58

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-08-29T00:35:15', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6cab6df7-e668-4cfc-a6f9-674e1cdc032a'	System	29 Aug 2020 05:35:22
User entered 'No interference with activity (1)'	System	29 Aug 2020 05:35:22

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-29T00:35:17', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6cab6df7-e668-4cfc-a6f9-674e1cdc032a'	System	29 Aug 2020 05:35:22
User entered '29 Aug 2020 00:35'	System	29 Aug 2020 05:35:22

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	28 Aug 2020 05:30:58

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 05:30:58



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 05:30:58
User entered 'Day 15'	System	28 Aug 2020 05:30:58

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-08-29T21:39:36', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '303137c3-3fcd-4552-9438-93fee8606b4'	System	30 Aug 2020 02:39:41
User entered 'None (0)'	System	30 Aug 2020 02:39:41

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-29T21:39:38', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '303137c3-3fcd-4552-9438-93fee8606b4'	System	30 Aug 2020 02:39:41
User entered '29 Aug 2020 21:39'	System	30 Aug 2020 02:39:41

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 05:30:58

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 05:30:58

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 02:39:08
User entered 'Day 8'	System	21 Aug 2020 02:39:08

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 26 Nov 2020 10:52:38

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 (e45941109fd6dbd5)', Time: '2020-08-22T21:46:55', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c54f8480-a27c-427e-bb61-aee4a5e0843c'	System	23 Aug 2020 02:47:01
User entered 'No (N)'	System	23 Aug 2020 02:47:01

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-22T21:46:59', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c54f8480-a27c-427e-bb61-ae4a5e0843c'	System	23 Aug 2020 02:47:01
User entered '22 Aug 2020 21:46'	System	23 Aug 2020 02:47:01



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 02:39:08

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 02:39:08

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	22 Aug 2020 05:04:53
User entered 'Day 9'	System	22 Aug 2020 05:04:53

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 26 Nov 2020 10:52:38

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 (e45941109fd6dbd5)', Time: '2020-08-23T23:42:36', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'eb9608b6-0c88-4421-83ad-2fafa34d6540'	System	24 Aug 2020 04:42:41
User entered 'No (N)'	System	24 Aug 2020 04:42:41

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-23T23:42:39', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'eb9608b6-0c88-4421-83ad-2fafa34d6540'	System	24 Aug 2020 04:42:41
User entered '23 Aug 2020 23:42'	System	24 Aug 2020 04:42:41

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 05:04:53

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 05:04:53

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Aug 2020 02:46:41
User entered 'Day 10'	System	23 Aug 2020 02:46:41



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 02:46:41

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 02:46:41

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 04:42:30
User entered 'Day 11'	System	24 Aug 2020 04:42:30

US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 26 Nov 2020 10:52:38

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 (e45941109fd6dbd5)', Time: '2020-08-25T23:57:01', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c9f3a042-6053-4017-bf7e-6282f084c4c6'	System	26 Aug 2020 04:57:09
User entered 'No (N)'	System	26 Aug 2020 04:57:09

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-25T23:57:04', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c9f3a042-6053-4017-bf7e-6282f084c4c6'	System	26 Aug 2020 04:57:09
User entered '25 Aug 2020 23:57'	System	26 Aug 2020 04:57:09

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 04:42:30

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 04:42:30

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 04:56:58
User entered 'Day 12'	System	26 Aug 2020 04:56:58



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	26 Aug 2020 04:56:58

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 04:56:58

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 04:56:58
User entered 'Day 13'	System	26 Aug 2020 04:56:58

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-08-28T00:31:03', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '519b7892-a326-4075-ad97-1538d81bcb32'	System	28 Aug 2020 05:31:11
User entered 'No (N)'	System	28 Aug 2020 05:31:11

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-28T00:31:06', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '519b7892-a326-4075-ad97-1538d81bcb32'	System	28 Aug 2020 05:31:11
User entered '28 Aug 2020 00:31'	System	28 Aug 2020 05:31:11

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 04:56:58

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 04:56:58

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 05:30:58
User entered 'Day 14'	System	28 Aug 2020 05:30:58



US3272169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 26 Nov 2020 10:52:38

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 (e45941109fd6dbd5)', Time: '2020-08-29T00:35:21', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'de9b301f-a027-46dc-8f8b-071358fb78cf'	System	29 Aug 2020 05:35:28
User entered 'No (N)'	System	29 Aug 2020 05:35:28

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-29T00:35:24', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'de9b301f-a027-46dc-8f8b-071358fb78cf'	System	29 Aug 2020 05:35:28
User entered '29 Aug 2020 00:35'	System	29 Aug 2020 05:35:28

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	28 Aug 2020 05:30:58

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 05:30:58

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 05:30:58
User entered 'Day 15'	System	28 Aug 2020 05:30:58

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-08-29T21:39:44', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '7abe10f9-5685-4f82-903a-05052186d626'	System	30 Aug 2020 02:39:47
User entered 'No (N)'	System	30 Aug 2020 02:39:47

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-08-29T21:39:46', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '7abe10f9-5685-4f82-903a-05052186d626'	System	30 Aug 2020 02:39:47
User entered '29 Aug 2020 21:39'	System	30 Aug 2020 02:39:47

**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 05:30:58



**US3272169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 05:30:58

**US3272169**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 15:04:27

**US3272169**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 15:04:27

**US3272169**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Sep 2020 15:04:27

**US3272169**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 15:04:27

US3272169

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 15:04:31

**US3272169**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:52:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Sep 2020 15:04:31

**US3272169**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 15:04:40



**US3272169**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 15:04:40

**US3272169**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Sep 2020 15:04:40

**US3272169**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 15:04:40

**US3272169**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:52:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 15:04:44

**US3272169**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:52:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Sep 2020 15:04:44

**US3272169**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 20:25:18

US3272169

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Sep 2020 20:25:29
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	09 Sep 2020 20:25:29
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 20:25:29
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Sep 2020 20:25:18
User entered '09 Sep 2020'	(b) (4), (b) (6)	09 Sep 2020 20:25:18

**US3272169**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Sep 2020 20:25:18



**US3272169**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 20:25:18

**US3272169**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:52:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 20:25:35

**US3272169**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:52:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Sep 2020 20:25:35

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:52:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 17:49:58

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:52:38**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 17:49:58

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:52:38**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Sep 2020 17:49:58

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:52:38**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	16 Sep 2020 17:49:58

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:38

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	16 Sep 2020 17:50:44



**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 17:50:44

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:52:38**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 17:50:44

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:52:38**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User entered '11:15'	(b) (4), (b) (6)	16 Sep 2020 17:50:44

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:15'	System	16 Sep 2020 17:50:44

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.4' C	(b) (4), (b) (6)	16 Sep 2020 17:50:44

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Sep 2020 17:50:44

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:52:38**

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 17:50:44

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '66'	(b) (4), (b) (6)	16 Sep 2020 17:50:44



**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Sep 2020 17:50:44

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '12'	(b) (4), (b) (6)	16 Sep 2020 17:50:44

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Sep 2020 17:50:44

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '84'	(b) (4), (b) (6)	16 Sep 2020 17:50:44

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Sep 2020 17:50:44

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '65'	(b) (4), (b) (6)	16 Sep 2020 17:50:44

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Sep 2020 17:50:44

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	16 Sep 2020 17:50:44



**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 17:50:44

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:52:38**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 17:50:44

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:26'	(b) (4), (b) (6)	16 Sep 2020 17:50:44

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:26'	System	16 Sep 2020 17:50:44

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.6' C	(b) (4), (b) (6)	16 Sep 2020 17:50:44

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Sep 2020 17:50:44

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:52:38**

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 17:50:44

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '68'	(b) (4), (b) (6)	16 Sep 2020 17:50:44



**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Sep 2020 17:50:44

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	16 Sep 2020 17:50:44

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Sep 2020 17:50:44

US3272169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '81'	(b) (4), (b) (6)	16 Sep 2020 17:50:44

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Sep 2020 17:50:44

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '65'	(b) (4), (b) (6)	16 Sep 2020 17:50:44

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Sep 2020 17:50:44

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 10:52:38**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 17:50:50



**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 10:52:38**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User entered '16 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 17:50:50

US3272169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:52:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 17:06:49

US3272169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:52:38

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 17:06:49

US3272169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:52:38

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)	16 Sep 2020 17:06:49

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:52:38**

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 17:06:49

US3272169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:52:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 17:06:49

US3272169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:52:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:06'	(b) (4), (b) (6)	16 Sep 2020 17:06:49

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:52:38**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:06'	System	16 Sep 2020 17:06:49



US3272169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:52:38

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	16 Sep 2020 17:06:49

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:52:38**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:52:38**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:52:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 17:51:10

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:52:38**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 17:51:10

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:52:38**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:20'	(b) (4), (b) (6)	16 Sep 2020 17:51:10

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:52:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:20'	System	16 Sep 2020 17:51:10

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 26 Nov 2020 10:52:38**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 17:51:19



**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	16 Sep 2020 17:51:19

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 17:51:19

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:52:38**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
User entered '11:25'	(b) (4), (b) (6)	16 Sep 2020 17:51:19

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:25'	System	16 Sep 2020 17:51:19

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	16 Sep 2020 17:51:19

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Sep 2020 17:51:19

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 17:51:19

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 17:51:19



US3272169

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 17:05:54

**US3272169**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:52:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Sep 2020 17:05:54

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 17:06:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T12:27:30', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5384f25d-b698-41bc-824a-8683dc5138cc'	System	16 Sep 2020 17:28:07
User entered 'Yes (Y)'	System	16 Sep 2020 17:28:07

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T12:27:40', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5384f25d-b698-41bc-824a-8683dc5138cc'	System	16 Sep 2020 17:28:07
User entered '98.0'	System	16 Sep 2020 17:28:07

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

**Was any MEDICATION TAKEN today for pain or fever?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T12:27:59', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5384f25d-b698-41bc-824a-8683dc5138cc'	System	16 Sep 2020 17:28:07
User entered 'No (N)'	System	16 Sep 2020 17:28:07

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T12:28:04', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5384f25d-b698-41bc-824a-8683dc5138cc'	System	16 Sep 2020 17:28:07
User entered '16 Sep 2020 12:28'	System	16 Sep 2020 17:28:07

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:26'	System	16 Sep 2020 17:06:49



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 14:56'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 17:06:49
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:48:18', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'ea95aa1f-fc97-4dae-bde0-d033465a5cad'	System	17 Sep 2020 02:48:36
User entered 'Yes (Y)'	System	17 Sep 2020 02:48:36

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:48:24', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'ea95aa1f-fc97-4dae-bde0-d033465a5cad'	System	17 Sep 2020 02:48:36
User entered '98.9'	System	17 Sep 2020 02:48:36

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

**Was any MEDICATION TAKEN today for pain or fever?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:48:28', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'ea95aa1f-fc97-4dae-bde0-d033465a5cad'	System	17 Sep 2020 02:48:36
User entered 'No (N)'	System	17 Sep 2020 02:48:36

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:48:34', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'ea95aa1f-fc97-4dae-bde0-d033465a5cad'	System	17 Sep 2020 02:48:36
User entered '16 Sep 2020 21:48'	System	17 Sep 2020 02:48:36

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 15:51'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 17:06:49



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 17:06:49
User entered 'Day 2'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:24:15', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '85e4f5a2-9bf9-4c1e-965c-b5e3124ce412'	System	18 Sep 2020 02:24:39
User entered 'Yes (Y)'	System	18 Sep 2020 02:24:39

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:24:20', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '85e4f5a2-9bf9-4c1e-965c-b5e3124ce412'	System	18 Sep 2020 02:24:39
User entered '99.1'	System	18 Sep 2020 02:24:39

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:52:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:24:23', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '85e4f5a2-9bf9-4c1e-965c-b5e3124ce412'	System	18 Sep 2020 02:24:39
User entered 'Yes (Y)'	System	18 Sep 2020 02:24:39

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:52:38

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 'pt contacted waiting on response ' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 23:08:13
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).	Ashley Bell (b) (4)	18 Sep 2020 19:20:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:24:30', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '85e4f5a2-9bf9-4c1e-965c-b5e3124ce412'	System	18 Sep 2020 02:24:39
User entered '1'	System	18 Sep 2020 02:24:39

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:24:30', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '85e4f5a2-9bf9-4c1e-965c-b5e3124ce412'	System	18 Sep 2020 02:24:39
User entered '0'	System	18 Sep 2020 02:24:39

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:24:36', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '85e4f5a2-9bf9-4c1e-965c-b5e3124ce412'	System	18 Sep 2020 02:24:39
User entered '17 Sep 2020 21:24'	System	18 Sep 2020 02:24:39

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 17:06:49



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 17:06:49
User entered 'Day 3'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:38:51', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4f9436dc-5162-4898-bd90-b244525d0a00'	System	19 Sep 2020 04:39:10
User entered 'Yes (Y)'	System	19 Sep 2020 04:39:10

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:38:57', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4f9436dc-5162-4898-bd90-b244525d0a00'	System	19 Sep 2020 04:39:10
User entered '99.3'	System	19 Sep 2020 04:39:10

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:52:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:39:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4f9436dc-5162-4898-bd90-b244525d0a00'	System	19 Sep 2020 04:39:10
User entered 'Yes (Y)'	System	19 Sep 2020 04:39:10

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:52:38

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 'updated con meds' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 23:08:34
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 (e45941109fd6dbd5)', Time: '2020-09-18T23:39:03', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4f9436dc-5162-4898-bd90-b244525d0a00'	System	19 Sep 2020 04:39:10
User entered '1'	System	19 Sep 2020 04:39:10

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:39:03', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4f9436dc-5162-4898-bd90-b244525d0a00'	System	19 Sep 2020 04:39:10
User entered '0'	System	19 Sep 2020 04:39:10

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:39:07', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4f9436dc-5162-4898-bd90-b244525d0a00'	System	19 Sep 2020 04:39:10
User entered '18 Sep 2020 23:39'	System	19 Sep 2020 04:39:10



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 17:06:49
User entered 'Day 4'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:13', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f4c45a08-2c7c-4de1-8d25-605f244b9268'	System	20 Sep 2020 02:49:33
User entered 'Yes (Y)'	System	20 Sep 2020 02:49:33

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:19', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f4c45a08-2c7c-4de1-8d25-605f244b9268'	System	20 Sep 2020 02:49:33
User entered '98.7'	System	20 Sep 2020 02:49:33

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

**Was any MEDICATION TAKEN today for pain or fever?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:22', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f4c45a08-2c7c-4de1-8d25-605f244b9268'	System	20 Sep 2020 02:49:33
User entered 'Yes (Y)'	System	20 Sep 2020 02:49:33

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:52:38

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 'updated con meds' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 23:08:53
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:25', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f4c45a08-2c7c-4de1-8d25-605f244b9268'	System	20 Sep 2020 02:49:33
User entered '1'	System	20 Sep 2020 02:49:33

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:25', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f4c45a08-2c7c-4de1-8d25-605f244b9268'	System	20 Sep 2020 02:49:33
User entered '0'	System	20 Sep 2020 02:49:33



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:31', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f4c45a08-2c7c-4de1-8d25-605f244b9268'	System	20 Sep 2020 02:49:33
User entered '19 Sep 2020 21:49'	System	20 Sep 2020 02:49:33

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 17:06:49
User entered 'Day 5'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:58:11', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '19987506-ec34-48fd-a126-7b504978bdf7'	System	21 Sep 2020 04:58:32
User entered 'Yes (Y)'	System	21 Sep 2020 04:58:32

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:58:17', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '19987506-ec34-48fd-a126-7b504978bdf7'	System	21 Sep 2020 04:58:32
User entered '98.9'	System	21 Sep 2020 04:58:32

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:52:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:58:20', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '19987506-ec34-48fd-a126-7b504978bdf7'	System	21 Sep 2020 04:58:32
User entered 'Yes (Y)'	System	21 Sep 2020 04:58:32

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:52:38

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 'updated con meds' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 23:09:12
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 (e45941109fd6dbd5)', Time: '2020-09-20T23:58:23', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '19987506-ec34-48fd-a126-7b504978bdf7'	System	21 Sep 2020 04:58:32
User entered '1'	System	21 Sep 2020 04:58:32



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:58:23', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '19987506-ec34-48fd-a126-7b504978bdf7'	System	21 Sep 2020 04:58:32
User entered '0'	System	21 Sep 2020 04:58:32

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:58:27', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '19987506-ec34-48fd-a126-7b504978bdf7'	System	21 Sep 2020 04:58:32
User entered '20 Sep 2020 23:58'	System	21 Sep 2020 04:58:32

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 17:06:49
User entered 'Day 6'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:31:25', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9e808397-393b-43da-970a-b91273ac2110'	System	22 Sep 2020 02:31:45
User entered 'Yes (Y)'	System	22 Sep 2020 02:31:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:31:34', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9e808397-393b-43da-970a-b91273ac2110'	System	22 Sep 2020 02:31:45
User entered '99.0'	System	22 Sep 2020 02:31:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

**Was any MEDICATION TAKEN today for pain or fever?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:31:37', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9e808397-393b-43da-970a-b91273ac2110'	System	22 Sep 2020 02:31:45
User entered 'Yes (Y)'	System	22 Sep 2020 02:31:45



US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:52:38

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 23:09:29
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 'updated' (Site from System).	Kayla Flege (b) (4)	25 Sep 2020 19:22:20
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	22 Sep 2020 02:31:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:31:40', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9e808397-393b-43da-970a-b91273ac2110'	System	22 Sep 2020 02:31:45
User entered '1'	System	22 Sep 2020 02:31:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:31:40', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9e808397-393b-43da-970a-b91273ac2110'	System	22 Sep 2020 02:31:45
User entered '0'	System	22 Sep 2020 02:31:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:31:43', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9e808397-393b-43da-970a-b91273ac2110'	System	22 Sep 2020 02:31:45
User entered '21 Sep 2020 21:31'	System	22 Sep 2020 02:31:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 17:06:49
User entered 'Day 7'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:19:39', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '81623b35-6d2f-477a-a94c-bf7ffc4efcc3'	System	23 Sep 2020 04:20:03
User entered 'Yes (Y)'	System	23 Sep 2020 04:20:03

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:19:45', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '81623b35-6d2f-477a-a94c-bf7ffc4efcc3'	System	23 Sep 2020 04:20:03
User entered '99.0'	System	23 Sep 2020 04:20:03



US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:52:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:19:47', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '81623b35-6d2f-477a-a94c-bf7ffc4efcc3'	System	23 Sep 2020 04:20:03
User entered 'Yes (Y)'	System	23 Sep 2020 04:20:03

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:52:38

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 'updated' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 23:09:53
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:19:54', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '81623b35-6d2f-477a-a94c-bf7ffc4efcc3'	Kayla Flege (b) (4)	25 Sep 2020 19:22:29
User entered '1'	System	23 Sep 2020 04:20:03
	System	23 Sep 2020 04:20:03
	System	23 Sep 2020 04:20:03

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:19:54', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '81623b35-6d2f-477a-a94c-bf7ffc4efcc3'	System	23 Sep 2020 04:20:03
User entered '0'	System	23 Sep 2020 04:20:03

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:19:58', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '81623b35-6d2f-477a-a94c-bf7ffc4efcc3'	System	23 Sep 2020 04:20:03
User entered '22 Sep 2020 23:19'	System	23 Sep 2020 04:20:03

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 02:31:45
User entered 'Day 8'	System	22 Sep 2020 02:31:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-23T21:59:45', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '88b6982e-6c7c-4c23-b2f9-ae417c63fc5a'	System	24 Sep 2020 03:00:24
User entered 'Yes (Y)'	System	24 Sep 2020 03:00:24



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-23T21:59:51', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '88b6982e-6c7c-4c23-b2f9-ae417c63fc5a'	System	24 Sep 2020 03:00:24
User entered '98.9'	System	24 Sep 2020 03:00:24

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 26 Nov 2020 10:52:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-23T21:59:54', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '88b6982e-6c7c-4c23-b2f9-ae417c63fc5a'	System	24 Sep 2020 03:00:24
User entered 'Yes (Y)'	System	24 Sep 2020 03:00:24

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 26 Nov 2020 10:52:38

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 'updated' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 23:10:11
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 (e45941109fd6dbd5)', Time: '2020-09-23T21:59:57', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '88b6982e-6c7c-4c23-b2f9-ae417c63fc5a'	Kayla Flege (b) (4)	25 Sep 2020 19:22:39
User entered '1'	System	24 Sep 2020 03:00:24
	System	24 Sep 2020 03:00:24
	System	24 Sep 2020 03:00:24

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-23T21:59:57', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '88b6982e-6c7c-4c23-b2f9-ae417c63fc5a'	System	24 Sep 2020 03:00:24
User entered '0'	System	24 Sep 2020 03:00:24

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-23T21:59:59', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '88b6982e-6c7c-4c23-b2f9-ae417c63fc5a'	System	24 Sep 2020 03:00:24
User entered '23 Sep 2020 21:59'	System	24 Sep 2020 03:00:24

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 02:31:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 02:31:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 04:20:03
User entered 'Day 9'	System	23 Sep 2020 04:20:03



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-24T22:31:59', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '49ba2e32-4475-491a-952b-2832be941dc9'	System	25 Sep 2020 03:32:16
User entered 'Yes (Y)'	System	25 Sep 2020 03:32:16

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-24T22:32:05', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '49ba2e32-4475-491a-952b-2832be941dc9'	System	25 Sep 2020 03:32:16
User entered '99.0'	System	25 Sep 2020 03:32:16

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 26 Nov 2020 10:52:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-24T22:32:08', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '49ba2e32-4475-491a-952b-2832be941dc9'	System	25 Sep 2020 03:32:16
User entered 'Yes (Y)'	System	25 Sep 2020 03:32:16

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 26 Nov 2020 10:52:38

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 23:10:30
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 'updated' (Site from System).	Kayla Flege (b) (4)	25 Sep 2020 19:22:46
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	25 Sep 2020 03:32:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-24T22:32:10', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '49ba2e32-4475-491a-952b-2832be941dc9'	System	25 Sep 2020 03:32:16
User entered '1'	System	25 Sep 2020 03:32:16

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-24T22:32:10', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '49ba2e32-4475-491a-952b-2832be941dc9'	System	25 Sep 2020 03:32:16
User entered '0'	System	25 Sep 2020 03:32:16

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-24T22:32:13', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '49ba2e32-4475-491a-952b-2832be941dc9'	System	25 Sep 2020 03:32:16
User entered '24 Sep 2020 22:32'	System	25 Sep 2020 03:32:16

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 04:20:03

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 04:20:03



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 03:00:24
User entered 'Day 10'	System	24 Sep 2020 03:00:24

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-25T23:20:40', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '8593fe65-33ce-428b-8a1b-b350f7f66af3'	System	26 Sep 2020 04:20:59
User entered 'Yes (Y)'	System	26 Sep 2020 04:20:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-25T23:20:44', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '8593fe65-33ce-428b-8a1b-b350f7f66af3'	System	26 Sep 2020 04:20:59
User entered '99.9'	System	26 Sep 2020 04:20:59

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(10)

Generated On: 26 Nov 2020 10:52:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-25T23:20:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '8593fe65-33ce-428b-8a1b-b350f7f66af3'	System	26 Sep 2020 04:20:59
User entered 'Yes (Y)'	System	26 Sep 2020 04:20:59

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(10)

Generated On: 26 Nov 2020 10:52:38

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 'con meds updated' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 23:10:49
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 (e45941109fd6dbd5)', Time: '2020-09-25T23:20:52', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '8593fe65-33ce-428b-8a1b-b350f7f66af3'	System	26 Sep 2020 04:20:59
User entered '1'	System	26 Sep 2020 04:20:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-25T23:20:52', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '8593fe65-33ce-428b-8a1b-b350f7f66af3'	System	26 Sep 2020 04:20:59
User entered '0'	System	26 Sep 2020 04:20:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-25T23:20:54', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '8593fe65-33ce-428b-8a1b-b350f7f66af3'	System	26 Sep 2020 04:20:59
User entered '25 Sep 2020 23:20'	System	26 Sep 2020 04:20:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 03:00:24



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 03:00:24

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 03:32:16
User entered 'Day 11'	System	25 Sep 2020 03:32:16

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-26T21:31:27', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '7cb987b5-96d4-4536-a6d7-b35b3b7a7573'	System	27 Sep 2020 02:31:45
User entered 'Yes (Y)'	System	27 Sep 2020 02:31:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-26T21:31:33', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '7cb987b5-96d4-4536-a6d7-b35b3b7a7573'	System	27 Sep 2020 02:31:45
User entered '98.7'	System	27 Sep 2020 02:31:45

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(11)

Generated On: 26 Nov 2020 10:52:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-26T21:31:37', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '7cb987b5-96d4-4536-a6d7-b35b3b7a7573'	System	27 Sep 2020 02:31:45
User entered 'Yes (Y)'	System	27 Sep 2020 02:31:45

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(11)

Generated On: 26 Nov 2020 10:52:38

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 'Acetaminophen for headache 1000 mg ' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 23:11:05
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 (e45941109fd6dbd5)', Time: '2020-09-26T21:31:40', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '7cb987b5-96d4-4536-a6d7-b35b3b7a7573'	System	27 Sep 2020 02:31:45
User entered '1'	System	27 Sep 2020 02:31:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-26T21:31:40', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '7cb987b5-96d4-4536-a6d7-b35b3b7a7573'	System	27 Sep 2020 02:31:45
User entered '0'	System	27 Sep 2020 02:31:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-26T21:31:43', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '7cb987b5-96d4-4536-a6d7-b35b3b7a7573'	System	27 Sep 2020 02:31:45
User entered '26 Sep 2020 21:31'	System	27 Sep 2020 02:31:45



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 03:32:16

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 03:32:16

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 04:20:59
User entered 'Day 12'	System	26 Sep 2020 04:20:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-27T23:52:28', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9b1e9b18-810c-4f87-87ce-fe8ba5f13395'	System	28 Sep 2020 04:52:43
User entered 'Yes (Y)'	System	28 Sep 2020 04:52:43

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-27T23:52:33', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9b1e9b18-810c-4f87-87ce-fe8ba5f13395'	System	28 Sep 2020 04:52:43
User entered '98.8'	System	28 Sep 2020 04:52:43

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(12)

Generated On: 26 Nov 2020 10:52:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-27T23:52:36', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9b1e9b18-810c-4f87-87ce-fe8ba5f13395'	System	28 Sep 2020 04:52:43
User entered 'Yes (Y)'	System	28 Sep 2020 04:52:43

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(12)

Generated On: 26 Nov 2020 10:52:38

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 'Acetaminophen for headache 1000 mg ' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 23:11:22
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 (e45941109fd6dbd5)', Time: '2020-09-27T23:52:39', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9b1e9b18-810c-4f87-87ce-fe8ba5f13395'	System	28 Sep 2020 04:52:43
User entered '1'	System	28 Sep 2020 04:52:43

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-27T23:52:39', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9b1e9b18-810c-4f87-87ce-fe8ba5f13395'	System	28 Sep 2020 04:52:43
User entered '0'	System	28 Sep 2020 04:52:43



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-27T23:52:41', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9b1e9b18-810c-4f87-87ce-fe8ba5f13395'	System	28 Sep 2020 04:52:43
User entered '27 Sep 2020 23:52'	System	28 Sep 2020 04:52:43

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 04:20:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 04:20:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	27 Sep 2020 02:31:45
User entered 'Day 13'	System	27 Sep 2020 02:31:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-28T21:15:38', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'dda9ae64-fe90-43a3-8977-ce0b8e6729c4'	System	29 Sep 2020 02:15:54
User entered 'Yes (Y)'	System	29 Sep 2020 02:15:54

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-28T21:15:43', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'dda9ae64-fe90-43a3-8977-ce0b8e6729c4'	System	29 Sep 2020 02:15:54
User entered '98.9'	System	29 Sep 2020 02:15:54

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(13)

Generated On: 26 Nov 2020 10:52:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-28T21:15:46', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'dda9ae64-fe90-43a3-8977-ce0b8e6729c4'	System	29 Sep 2020 02:15:54
User entered 'Yes (Y)'	System	29 Sep 2020 02:15:54

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(13)

Generated On: 26 Nov 2020 10:52:38

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 'Acetaminophen for headache 1000 mg ' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 23:11:36
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 (e45941109fd6dbd5)', Time: '2020-09-28T21:15:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'dda9ae64-fe90-43a3-8977-ce0b8e6729c4'	System	29 Sep 2020 02:15:54
User entered '1'	System	29 Sep 2020 02:15:54



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-28T21:15:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'dda9ae64-fe90-43a3-8977-ce0b8e6729c4'	System	29 Sep 2020 02:15:54
User entered '0'	System	29 Sep 2020 02:15:54

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-28T21:15:51', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'dda9ae64-fe90-43a3-8977-ce0b8e6729c4'	System	29 Sep 2020 02:15:54
User entered '28 Sep 2020 21:15'	System	29 Sep 2020 02:15:54

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	27 Sep 2020 02:31:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	27 Sep 2020 02:31:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 04:52:43
User entered 'Day 14'	System	28 Sep 2020 04:52:43

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-29T22:18:34', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2d09c252-2a5e-4ce1-b82f-a070d3356365'	System	30 Sep 2020 03:18:52
User entered 'Yes (Y)'	System	30 Sep 2020 03:18:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-29T22:18:39', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2d09c252-2a5e-4ce1-b82f-a070d3356365'	System	30 Sep 2020 03:18:52
User entered '98.9'	System	30 Sep 2020 03:18:52

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(14)

Generated On: 26 Nov 2020 10:52:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-29T22:18:42', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2d09c252-2a5e-4ce1-b82f-a070d3356365'	System	30 Sep 2020 03:18:52
User entered 'Yes (Y)'	System	30 Sep 2020 03:18:52



US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(14)

Generated On: 26 Nov 2020 10:52:38

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 'Acetaminophen for headache 1000 mg ' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 23:12:36
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 (e45941109fd6dbd5)', Time: '2020-09-29T22:18:44', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2d09c252-2a5e-4ce1-b82f-a070d3356365'	System	30 Sep 2020 03:18:52
User entered '1'	System	30 Sep 2020 03:18:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-29T22:18:44', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2d09c252-2a5e-4ce1-b82f-a070d3356365'	System	30 Sep 2020 03:18:52
User entered '0'	System	30 Sep 2020 03:18:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-29T22:18:50', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2d09c252-2a5e-4ce1-b82f-a070d3356365'	System	30 Sep 2020 03:18:52
User entered '29 Sep 2020 22:18'	System	30 Sep 2020 03:18:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 04:52:43

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 04:52:43

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 02:15:54
User entered 'Day 15'	System	29 Sep 2020 02:15:54

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-30T20:03:33', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b758bcb3-e86c-40c7-9507-eb8903ea8104'	System	01 Oct 2020 01:03:52
User entered 'Yes (Y)'	System	01 Oct 2020 01:03:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-30T20:03:40', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b758bcb3-e86c-40c7-9507-eb8903ea8104'	System	01 Oct 2020 01:03:52
User entered '98.7'	System	01 Oct 2020 01:03:52



US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(15)

Generated On: 26 Nov 2020 10:52:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-30T20:03:43', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b758bcb3-e86c-40c7-9507-eb8903ea8104'	System	01 Oct 2020 01:03:52
User entered 'Yes (Y)'	System	01 Oct 2020 01:03:52

US3272169

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(15)

Generated On: 26 Nov 2020 10:52:38

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 'Acetaminophen for headache 1000 mg ' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 23:12:53
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-30T20:03:45', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b758bcb3-e86c-40c7-9507-eb8903ea8104'	System	01 Oct 2020 01:03:52
User entered '1'	System	01 Oct 2020 01:03:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-30T20:03:45', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b758bcb3-e86c-40c7-9507-eb8903ea8104'	System	01 Oct 2020 01:03:52
User entered '0'	System	01 Oct 2020 01:03:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-30T20:03:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b758bcb3-e86c-40c7-9507-eb8903ea8104'	System	01 Oct 2020 01:03:52
User entered '30 Sep 2020 20:03'	System	01 Oct 2020 01:03:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 02:15:54

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 02:15:54

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 03:18:52
User entered 'Day 16'	System	30 Sep 2020 03:18:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-01T22:27:23', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c2e0b712-884a-4078-87dc-3aeba9c9a25b'	System	02 Oct 2020 03:27:36
User entered 'Yes (Y)'	System	02 Oct 2020 03:27:36



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-01T22:27:29', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c2e0b712-884a-4078-87dc-3aeba9c9a25b'	System	02 Oct 2020 03:27:36
User entered '98.6'	System	02 Oct 2020 03:27:36

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

**Was any MEDICATION TAKEN today for pain or fever?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-01T22:27:32', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c2e0b712-884a-4078-87dc-3aeba9c9a25b'	System	02 Oct 2020 03:27:36
User entered 'No (N)'	System	02 Oct 2020 03:27:36

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-01T22:27:34', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c2e0b712-884a-4078-87dc-3aeba9c9a25b'	System	02 Oct 2020 03:27:36
User entered '01 Oct 2020 22:27'	System	02 Oct 2020 03:27:36

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 03:18:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 03:18:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 17:06:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-09-16T13:05:10', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f7286483-2821-4d61-8999-ec33ff84bd28'	System	16 Sep 2020 18:05:30
User entered 'None (1)'	System	16 Sep 2020 18:05:30

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T13:05:16', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f7286483-2821-4d61-8999-ec33ff84bd28'	System	16 Sep 2020 18:05:30
User entered 'No (N)'	System	16 Sep 2020 18:05:30



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T13:05:19', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f7286483-2821-4d61-8999-ec33ff84bd28'	System	16 Sep 2020 18:05:30
User entered 'No (N)'	System	16 Sep 2020 18:05:30

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-09-16T13:05:22', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f7286483-2821-4d61-8999-ec33ff84bd28'	System	16 Sep 2020 18:05:30
User entered 'None (1)'	System	16 Sep 2020 18:05:30

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T13:05:26', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f7286483-2821-4d61-8999-ec33ff84bd28'	System	16 Sep 2020 18:05:30
User entered '16 Sep 2020 13:05'	System	16 Sep 2020 18:05:30

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:26'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 14:56'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 17:06:49
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-09-16T21:48:41', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '27a59b0a-6bd8-44c2-a9f1-bef295d3319f'	System	17 Sep 2020 02:49:10
User entered 'None (1)'	System	17 Sep 2020 02:49:10

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:48:45', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '27a59b0a-6bd8-44c2-a9f1-bef295d3319f'	System	17 Sep 2020 02:49:10
User entered 'No (N)'	System	17 Sep 2020 02:49:10



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:49:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '27a59b0a-6bd8-44c2-a9f1-bef295d3319f'	System	17 Sep 2020 02:49:10
User entered 'No (N)'	System	17 Sep 2020 02:49:10

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-09-16T21:49:04', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '27a59b0a-6bd8-44c2-a9f1-bef295d3319f'	System	17 Sep 2020 02:49:10
User entered 'None (1)'	System	17 Sep 2020 02:49:10

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:49:07', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '27a59b0a-6bd8-44c2-a9f1-bef295d3319f'	System	17 Sep 2020 02:49:10
User entered '16 Sep 2020 21:49'	System	17 Sep 2020 02:49:10

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 15:51'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 17:06:49
User entered 'Day 2'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-09-17T21:24:50', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'ed496555-c58c-4fb7-a327-5f986c678256'	System	18 Sep 2020 02:25:15
User entered 'Does not interfere with activity (2)'	System	18 Sep 2020 02:25:15

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:24:53', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'ed496555-c58c-4fb7-a327-5f986c678256'	System	18 Sep 2020 02:25:15
User entered 'No (N)'	System	18 Sep 2020 02:25:15



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:25:05', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'ed496555-c58c-4fb7-a327-5f986c678256'	System	18 Sep 2020 02:25:15
User entered 'No (N)'	System	18 Sep 2020 02:25:15

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-09-17T21:25:08', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'ed496555-c58c-4fb7-a327-5f986c678256'	System	18 Sep 2020 02:25:15
User entered 'None (1)'	System	18 Sep 2020 02:25:15

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:25:10', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'ed496555-c58c-4fb7-a327-5f986c678256'	System	18 Sep 2020 02:25:15
User entered '17 Sep 2020 21:25'	System	18 Sep 2020 02:25:15

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 17:06:49
User entered 'Day 3'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-09-18T23:39:13', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9e8a8af3-41db-40c7-8c8f-05683fc265aa'	System	19 Sep 2020 04:39:26
User entered 'Does not interfere with activity (2)'	System	19 Sep 2020 04:39:26

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:39:16', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9e8a8af3-41db-40c7-8c8f-05683fc265aa'	System	19 Sep 2020 04:39:26
User entered 'No (N)'	System	19 Sep 2020 04:39:26



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:39:19', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9e8a8af3-41db-40c7-8c8f-05683fc265aa'	System	19 Sep 2020 04:39:26
User entered 'No (N)'	System	19 Sep 2020 04:39:26

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-09-18T23:39:21', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9e8a8af3-41db-40c7-8c8f-05683fc265aa'	System	19 Sep 2020 04:39:26
User entered 'None (1)'	System	19 Sep 2020 04:39:26

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:39:25', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9e8a8af3-41db-40c7-8c8f-05683fc265aa'	System	19 Sep 2020 04:39:26
User entered '18 Sep 2020 23:39'	System	19 Sep 2020 04:39:26

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 17:06:49
User entered 'Day 4'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-09-19T21:48:54', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'bd822b16-960e-4411-a2cf-e73a56a10a0b'	System	20 Sep 2020 02:49:10
User entered 'Does not interfere with activity (2)'	System	20 Sep 2020 02:49:10

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:48:57', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'bd822b16-960e-4411-a2cf-e73a56a10a0b'	System	20 Sep 2020 02:49:10
User entered 'No (N)'	System	20 Sep 2020 02:49:10



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'bd822b16-960e-4411-a2cf-e73a56a10a0b'	System	20 Sep 2020 02:49:10
User entered 'No (N)'	System	20 Sep 2020 02:49:10

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-09-19T21:49:03', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'bd822b16-960e-4411-a2cf-e73a56a10a0b'	System	20 Sep 2020 02:49:10
User entered 'None (1)'	System	20 Sep 2020 02:49:10

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:07', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'bd822b16-960e-4411-a2cf-e73a56a10a0b'	System	20 Sep 2020 02:49:10
User entered '19 Sep 2020 21:49'	System	20 Sep 2020 02:49:10

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 17:06:49
User entered 'Day 5'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-09-20T23:58:32', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd9c27126-18a7-4ad7-ac1a-6c543e5f56b2'	System	21 Sep 2020 04:58:44
User entered 'None (1)'	System	21 Sep 2020 04:58:44

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:58:35', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd9c27126-18a7-4ad7-ac1a-6c543e5f56b2'	System	21 Sep 2020 04:58:44
User entered 'No (N)'	System	21 Sep 2020 04:58:44



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:58:37', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd9c27126-18a7-4ad7-ac1a-6c543e5f56b2'	System	21 Sep 2020 04:58:44
User entered 'No (N)'	System	21 Sep 2020 04:58:44

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-20T23:58:40', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd9c27126-18a7-4ad7-ac1a-6c543e5f56b2'	System	21 Sep 2020 04:58:44
User entered 'None (1)'	System	21 Sep 2020 04:58:44

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:58:43', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd9c27126-18a7-4ad7-ac1a-6c543e5f56b2'	System	21 Sep 2020 04:58:44
User entered '20 Sep 2020 23:58'	System	21 Sep 2020 04:58:44

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 17:06:49
User entered 'Day 6'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-09-21T21:31:53', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '25f95f86-69dd-4093-9599-492c506ddb84'	System	22 Sep 2020 02:32:10
User entered 'None (1)'	System	22 Sep 2020 02:32:10

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:31:56', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '25f95f86-69dd-4093-9599-492c506ddb84'	System	22 Sep 2020 02:32:10
User entered 'No (N)'	System	22 Sep 2020 02:32:10



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:31:59', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '25f95f86-69dd-4093-9599-492c506ddb84'	System	22 Sep 2020 02:32:10
User entered 'No (N)'	System	22 Sep 2020 02:32:10

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-21T21:32:01', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '25f95f86-69dd-4093-9599-492c506ddb84'	System	22 Sep 2020 02:32:10
User entered 'None (1)'	System	22 Sep 2020 02:32:10

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:32:04', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '25f95f86-69dd-4093-9599-492c506ddb84'	System	22 Sep 2020 02:32:10
User entered '21 Sep 2020 21:32'	System	22 Sep 2020 02:32:10

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 17:06:49
User entered 'Day 7'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-09-22T23:20:04', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '3fe76b85-1f30-4669-8f83-4b42e49b8416'	System	23 Sep 2020 04:20:22
User entered 'None (1)'	System	23 Sep 2020 04:20:22

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:20:07', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '3fe76b85-1f30-4669-8f83-4b42e49b8416'	System	23 Sep 2020 04:20:22
User entered 'No (N)'	System	23 Sep 2020 04:20:22



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:20:09', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '3fe76b85-1f30-4669-8f83-4b42e49b8416'	System	23 Sep 2020 04:20:22
User entered 'No (N)'	System	23 Sep 2020 04:20:22

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-09-22T23:20:14', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '3fe76b85-1f30-4669-8f83-4b42e49b8416'	System	23 Sep 2020 04:20:22
User entered 'None (1)'	System	23 Sep 2020 04:20:22

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:20:18', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '3fe76b85-1f30-4669-8f83-4b42e49b8416'	System	23 Sep 2020 04:20:22
User entered '22 Sep 2020 23:20'	System	23 Sep 2020 04:20:22

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 17:06:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T13:05:31', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1a4ddcb5-16fd-419e-b97c-af7df11eac32'	System	16 Sep 2020 18:05:54
User entered 'None (0)'	System	16 Sep 2020 18:05:54

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T13:05:36', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1a4ddcb5-16fd-419e-b97c-af7df11eac32'	System	16 Sep 2020 18:05:54
User entered 'None (0)'	System	16 Sep 2020 18:05:54



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T13:05:39', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1a4ddcb5-16fd-419e-b97c-af7df11eac32'	System	16 Sep 2020 18:05:54
User entered 'None (0)'	System	16 Sep 2020 18:05:54

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T13:05:41', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1a4ddcb5-16fd-419e-b97c-af7df11eac32'	System	16 Sep 2020 18:05:54
User entered 'None (0)'	System	16 Sep 2020 18:05:54

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T13:05:43', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1a4ddcb5-16fd-419e-b97c-af7df11eac32'	System	16 Sep 2020 18:05:54
User entered 'None (0)'	System	16 Sep 2020 18:05:54

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T13:05:46', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1a4ddcb5-16fd-419e-b97c-af7df11eac32'	System	16 Sep 2020 18:05:54
User entered 'None (0)'	System	16 Sep 2020 18:05:54

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-16T13:05:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1a4ddcb5-16fd-419e-b97c-af7df11eac32'	System	16 Sep 2020 18:05:54
User entered 'No (N)'	System	16 Sep 2020 18:05:54

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T13:05:52', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1a4ddcb5-16fd-419e-b97c-af7df11eac32'	System	16 Sep 2020 18:05:54
User entered '16 Sep 2020 13:05'	System	16 Sep 2020 18:05:54

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:26'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 14:56'	System	16 Sep 2020 17:06:49



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 17:06:49
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:49:13', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0cca70ba-520e-4ed5-b0f8-f8ebedf358b4'	System	17 Sep 2020 02:49:36
User entered 'No interference with activity (1)'	System	17 Sep 2020 02:49:36

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:49:16', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0cca70ba-520e-4ed5-b0f8-f8ebedf358b4'	System	17 Sep 2020 02:49:36
User entered 'No interference with activity (1)'	System	17 Sep 2020 02:49:36

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:49:19', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0cca70ba-520e-4ed5-b0f8-f8ebedf358b4'	System	17 Sep 2020 02:49:36
User entered 'None (0)'	System	17 Sep 2020 02:49:36

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:49:21', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0cca70ba-520e-4ed5-b0f8-f8ebedf358b4'	System	17 Sep 2020 02:49:36
User entered 'None (0)'	System	17 Sep 2020 02:49:36

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:49:24', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0cca70ba-520e-4ed5-b0f8-f8ebedf358b4'	System	17 Sep 2020 02:49:36
User entered 'None (0)'	System	17 Sep 2020 02:49:36

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:49:26', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0cca70ba-520e-4ed5-b0f8-f8ebedf358b4'	System	17 Sep 2020 02:49:36
User entered 'None (0)'	System	17 Sep 2020 02:49:36

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-16T21:49:29', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0cca70ba-520e-4ed5-b0f8-f8ebedf358b4'	System	17 Sep 2020 02:49:36
User entered 'No (N)'	System	17 Sep 2020 02:49:36



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-16T21:49:32', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0cca70ba-520e-4ed5-b0f8-f8ebedf358b4'	System	17 Sep 2020 02:49:36
User entered '16 Sep 2020 21:49'	System	17 Sep 2020 02:49:36

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 15:51'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 17:06:49
User entered 'Day 2'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:25:16', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'e84aaaa4-4047-4de6-a553-75d1bf6f7327'	System	18 Sep 2020 02:25:48
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	18 Sep 2020 02:25:48

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:25:22', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'e84aaaa4-4047-4de6-a553-75d1bf6f7327'	System	18 Sep 2020 02:25:48
User entered 'No interference with activity (1)'	System	18 Sep 2020 02:25:48

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:25:28', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'e84aaaa4-4047-4de6-a553-75d1bf6f7327'	System	18 Sep 2020 02:25:48
User entered 'Some interference with activity (2)'	System	18 Sep 2020 02:25:48

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:25:33', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'e84aaaa4-4047-4de6-a553-75d1bf6f7327'	System	18 Sep 2020 02:25:48
User entered 'Some interference with activity (2)'	System	18 Sep 2020 02:25:48



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:25:37', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'e84aaaa4-4047-4de6-a553-75d1bf6f7327'	System	18 Sep 2020 02:25:48
User entered 'None (0)'	System	18 Sep 2020 02:25:48

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:25:39', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'e84aaaa4-4047-4de6-a553-75d1bf6f7327'	System	18 Sep 2020 02:25:48
User entered 'None (0)'	System	18 Sep 2020 02:25:48

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-17T21:25:42', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'e84aaaa4-4047-4de6-a553-75d1bf6f7327'	System	18 Sep 2020 02:25:48
User entered 'No (N)'	System	18 Sep 2020 02:25:48

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-17T21:25:45', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'e84aaaa4-4047-4de6-a553-75d1bf6f7327'	System	18 Sep 2020 02:25:48
User entered '17 Sep 2020 21:25'	System	18 Sep 2020 02:25:48

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 17:06:49
User entered 'Day 3'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:39:32', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f747f05c-ef73-410b-b850-6f6860fe7853'	System	19 Sep 2020 04:39:59
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	19 Sep 2020 04:39:59



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:39:35', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f747f05c-ef73-410b-b850-6f6860fe7853'	System	19 Sep 2020 04:39:59
User entered 'Some interference with activity (2)'	System	19 Sep 2020 04:39:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:39:39', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f747f05c-ef73-410b-b850-6f6860fe7853'	System	19 Sep 2020 04:39:59
User entered 'No interference with activity (1)'	System	19 Sep 2020 04:39:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:39:43', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f747f05c-ef73-410b-b850-6f6860fe7853'	System	19 Sep 2020 04:39:59
User entered 'No interference with activity (1)'	System	19 Sep 2020 04:39:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:39:46', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f747f05c-ef73-410b-b850-6f6860fe7853'	System	19 Sep 2020 04:39:59
User entered 'None (0)'	System	19 Sep 2020 04:39:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:39:48', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f747f05c-ef73-410b-b850-6f6860fe7853'	System	19 Sep 2020 04:39:59
User entered 'None (0)'	System	19 Sep 2020 04:39:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-18T23:39:51', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f747f05c-ef73-410b-b850-6f6860fe7853'	System	19 Sep 2020 04:39:59
User entered 'No (N)'	System	19 Sep 2020 04:39:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-18T23:39:55', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f747f05c-ef73-410b-b850-6f6860fe7853'	System	19 Sep 2020 04:39:59
User entered '18 Sep 2020 23:39'	System	19 Sep 2020 04:39:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 17:06:49



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 17:06:49
User entered 'Day 4'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:38', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6facc22b-0360-41ad-90ed-70da9c37fe53'	System	20 Sep 2020 02:50:01
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	20 Sep 2020 02:50:01

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:42', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6facc22b-0360-41ad-90ed-70da9c37fe53'	System	20 Sep 2020 02:50:01
User entered 'No interference with activity (1)'	System	20 Sep 2020 02:50:01

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:46', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6facc22b-0360-41ad-90ed-70da9c37fe53'	System	20 Sep 2020 02:50:01
User entered 'None (0)'	System	20 Sep 2020 02:50:01

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6facc22b-0360-41ad-90ed-70da9c37fe53'	System	20 Sep 2020 02:50:01
User entered 'No interference with activity (1)'	System	20 Sep 2020 02:50:01

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:51', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6facc22b-0360-41ad-90ed-70da9c37fe53'	System	20 Sep 2020 02:50:01
User entered 'None (0)'	System	20 Sep 2020 02:50:01

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:53', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6facc22b-0360-41ad-90ed-70da9c37fe53'	System	20 Sep 2020 02:50:01
User entered 'None (0)'	System	20 Sep 2020 02:50:01



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-19T21:49:56', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6facc22b-0360-41ad-90ed-70da9c37fe53'	System	20 Sep 2020 02:50:01
User entered 'No (N)'	System	20 Sep 2020 02:50:01

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-19T21:49:59', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6facc22b-0360-41ad-90ed-70da9c37fe53'	System	20 Sep 2020 02:50:01
User entered '19 Sep 2020 21:49'	System	20 Sep 2020 02:50:01

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 17:06:49
User entered 'Day 5'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:58:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a33d3603-2340-4943-86e0-b15ad8d9e119'	System	21 Sep 2020 04:59:14
User entered 'No interference with activity (1)'	System	21 Sep 2020 04:59:14

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:58:52', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a33d3603-2340-4943-86e0-b15ad8d9e119'	System	21 Sep 2020 04:59:14
User entered 'No interference with activity (1)'	System	21 Sep 2020 04:59:14

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:58:58', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a33d3603-2340-4943-86e0-b15ad8d9e119'	System	21 Sep 2020 04:59:14
User entered 'No interference with activity (1)'	System	21 Sep 2020 04:59:14



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:59:02', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a33d3603-2340-4943-86e0-b15ad8d9e119'	System	21 Sep 2020 04:59:14
User entered 'None (0)'	System	21 Sep 2020 04:59:14

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:59:04', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a33d3603-2340-4943-86e0-b15ad8d9e119'	System	21 Sep 2020 04:59:14
User entered 'None (0)'	System	21 Sep 2020 04:59:14

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:59:06', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a33d3603-2340-4943-86e0-b15ad8d9e119'	System	21 Sep 2020 04:59:14
User entered 'None (0)'	System	21 Sep 2020 04:59:14

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-20T23:59:09', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a33d3603-2340-4943-86e0-b15ad8d9e119'	System	21 Sep 2020 04:59:14
User entered 'No (N)'	System	21 Sep 2020 04:59:14

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-20T23:59:11', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a33d3603-2340-4943-86e0-b15ad8d9e119'	System	21 Sep 2020 04:59:14
User entered '20 Sep 2020 23:59'	System	21 Sep 2020 04:59:14

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 17:06:49
User entered 'Day 6'	System	16 Sep 2020 17:06:49



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:32:09', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1609a0cb-ff7d-4bda-aa0b-16de20624bd8'	System	22 Sep 2020 02:32:30
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	22 Sep 2020 02:32:30

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:32:14', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1609a0cb-ff7d-4bda-aa0b-16de20624bd8'	System	22 Sep 2020 02:32:30
User entered 'Some interference with activity (2)'	System	22 Sep 2020 02:32:30

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:32:17', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1609a0cb-ff7d-4bda-aa0b-16de20624bd8'	System	22 Sep 2020 02:32:30
User entered 'No interference with activity (1)'	System	22 Sep 2020 02:32:30

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:32:19', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1609a0cb-ff7d-4bda-aa0b-16de20624bd8'	System	22 Sep 2020 02:32:30
User entered 'None (0)'	System	22 Sep 2020 02:32:30

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:32:22', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1609a0cb-ff7d-4bda-aa0b-16de20624bd8'	System	22 Sep 2020 02:32:30
User entered 'None (0)'	System	22 Sep 2020 02:32:30

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:32:24', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1609a0cb-ff7d-4bda-aa0b-16de20624bd8'	System	22 Sep 2020 02:32:30
User entered 'None (0)'	System	22 Sep 2020 02:32:30

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-21T21:32:26', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1609a0cb-ff7d-4bda-aa0b-16de20624bd8'	System	22 Sep 2020 02:32:30
User entered 'No (N)'	System	22 Sep 2020 02:32:30

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-21T21:32:28', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1609a0cb-ff7d-4bda-aa0b-16de20624bd8'	System	22 Sep 2020 02:32:30
User entered '21 Sep 2020 21:32'	System	22 Sep 2020 02:32:30



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 17:06:49
User entered 'Day 7'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:20:31', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6e39cf43-a56a-45e6-9a84-0cc21e35455b'	System	23 Sep 2020 04:20:59
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	23 Sep 2020 04:20:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:20:34', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6e39cf43-a56a-45e6-9a84-0cc21e35455b'	System	23 Sep 2020 04:20:59
User entered 'Some interference with activity (2)'	System	23 Sep 2020 04:20:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:20:38', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6e39cf43-a56a-45e6-9a84-0cc21e35455b'	System	23 Sep 2020 04:20:59
User entered 'Some interference with activity (2)'	System	23 Sep 2020 04:20:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:20:44', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6e39cf43-a56a-45e6-9a84-0cc21e35455b'	System	23 Sep 2020 04:20:59
User entered 'Some interference with activity (2)'	System	23 Sep 2020 04:20:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:20:47', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6e39cf43-a56a-45e6-9a84-0cc21e35455b'	System	23 Sep 2020 04:20:59
User entered 'None (0)'	System	23 Sep 2020 04:20:59



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:20:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6e39cf43-a56a-45e6-9a84-0cc21e35455b'	System	23 Sep 2020 04:20:59
User entered 'None (0)'	System	23 Sep 2020 04:20:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-22T23:20:52', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6e39cf43-a56a-45e6-9a84-0cc21e35455b'	System	23 Sep 2020 04:20:59
User entered 'No (N)'	System	23 Sep 2020 04:20:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-22T23:20:55', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6e39cf43-a56a-45e6-9a84-0cc21e35455b'	System	23 Sep 2020 04:20:59
User entered '22 Sep 2020 23:20'	System	23 Sep 2020 04:20:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 17:06:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 02:32:30
User entered 'Day 8'	System	22 Sep 2020 02:32:30

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-23T22:00:10', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'dced4acd-204f-464f-8a46-27cd90a52551'	System	24 Sep 2020 03:00:26
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	24 Sep 2020 03:00:26

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-23T22:00:13', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'dced4acd-204f-464f-8a46-27cd90a52551'	System	24 Sep 2020 03:00:26
User entered '23 Sep 2020 22:00'	System	24 Sep 2020 03:00:26



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 02:32:30

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 02:32:30

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 04:20:59
User entered 'Day 9'	System	23 Sep 2020 04:20:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-24T22:32:20', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '60cf7f2c-3c3a-4da4-aae0-83683a411a06'	System	25 Sep 2020 03:32:27
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	25 Sep 2020 03:32:27

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-24T22:32:23', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '60cf7f2c-3c3a-4da4-aae0-83683a411a06'	System	25 Sep 2020 03:32:27
User entered '24 Sep 2020 22:32'	System	25 Sep 2020 03:32:27

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 04:20:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 04:20:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 03:00:26
User entered 'Day 10'	System	24 Sep 2020 03:00:26



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-25T23:20:59', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'fb540251-cceb-4241-93bb-9f4224faec5c'	System	26 Sep 2020 04:21:08
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	26 Sep 2020 04:21:08

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-25T23:21:01', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'fb540251-cceb-4241-93bb-9f4224faec5c'	System	26 Sep 2020 04:21:08
User entered '25 Sep 2020 23:21'	System	26 Sep 2020 04:21:08

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 03:00:26

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 03:00:26

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 03:32:27
User entered 'Day 11'	System	25 Sep 2020 03:32:27

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-26T21:31:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0d7e604d-2485-4696-9fa7-0168e2c91a25'	System	27 Sep 2020 02:31:53
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	27 Sep 2020 02:31:53

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-26T21:31:51', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0d7e604d-2485-4696-9fa7-0168e2c91a25'	System	27 Sep 2020 02:31:53
User entered '26 Sep 2020 21:31'	System	27 Sep 2020 02:31:53

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 03:32:27



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 03:32:27

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 04:21:08
User entered 'Day 12'	System	26 Sep 2020 04:21:08

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-27T23:52:47', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '02ecafb3-026d-42d3-a808-e320d3a16658'	System	28 Sep 2020 04:52:53
User entered 'No interference with activity (1)'	System	28 Sep 2020 04:52:53

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-27T23:52:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '02ecafb3-026d-42d3-a808-e320d3a16658'	System	28 Sep 2020 04:52:53
User entered '27 Sep 2020 23:52'	System	28 Sep 2020 04:52:53

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 04:21:08

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 04:21:08

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	27 Sep 2020 02:31:53
User entered 'Day 13'	System	27 Sep 2020 02:31:53

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-28T21:16:10', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '8edffc00-aa75-48f7-bbc4-e07db11c98dd'	System	29 Sep 2020 02:16:16
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	29 Sep 2020 02:16:16



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-28T21:16:13', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '8edffc00-aa75-48f7-bbc4-e07db11c98dd'	System	29 Sep 2020 02:16:16
User entered '28 Sep 2020 21:16'	System	29 Sep 2020 02:16:16

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	27 Sep 2020 02:31:53

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	27 Sep 2020 02:31:53

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 04:52:53
User entered 'Day 14'	System	28 Sep 2020 04:52:53

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-29T22:18:56', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '7a06c8c0-6163-4953-916a-a070a9737bfc'	System	30 Sep 2020 03:19:03
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	30 Sep 2020 03:19:03

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-29T22:18:59', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '7a06c8c0-6163-4953-916a-a070a9737bfc'	System	30 Sep 2020 03:19:03
User entered '29 Sep 2020 22:18'	System	30 Sep 2020 03:19:03

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 04:52:53

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 04:52:53



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 02:16:16
User entered 'Day 15'	System	29 Sep 2020 02:16:16

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-30T20:03:53', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f4a6d0a1-4f28-48d2-943c-40f944bae002'	System	01 Oct 2020 01:03:59
User entered 'No interference with activity (1)'	System	01 Oct 2020 01:03:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-30T20:03:56', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f4a6d0a1-4f28-48d2-943c-40f944bae002'	System	01 Oct 2020 01:03:59
User entered '30 Sep 2020 20:03'	System	01 Oct 2020 01:03:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 02:16:16

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 02:16:16

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 03:19:03
User entered 'Day 16'	System	30 Sep 2020 03:19:03

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-01T22:27:40', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0f44b9d3-f1b1-40fb-bebb-6d88c3733119'	System	02 Oct 2020 03:27:45
User entered 'No interference with activity (1)'	System	02 Oct 2020 03:27:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-01T22:27:42', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0f44b9d3-f1b1-40fb-bebb-6d88c3733119'	System	02 Oct 2020 03:27:45
User entered '01 Oct 2020 22:27'	System	02 Oct 2020 03:27:45



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 03:19:03

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 03:19:03

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(17)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 01:03:59
User entered 'Day 17'	System	01 Oct 2020 01:03:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(17)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 01:03:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(17)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 01:03:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(18)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 03:27:45
User entered 'Day 18'	System	02 Oct 2020 03:27:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(18)**

**Generated On: 26 Nov 2020 10:52:38**

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-03T22:22:46', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'e2d0a044-6306-4613-81e9-4e653680f723'	System	04 Oct 2020 03:22:52
User entered 'No interference with activity (1)'	System	04 Oct 2020 03:22:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(18)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-03T22:22:50', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'e2d0a044-6306-4613-81e9-4e653680f723'	System	04 Oct 2020 03:22:52
User entered '03 Oct 2020 22:22'	System	04 Oct 2020 03:22:52



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(18)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 03:27:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(18)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 03:27:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(19)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Oct 2020 03:22:52
User entered 'Day 19'	System	04 Oct 2020 03:22:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(19)**

**Generated On: 26 Nov 2020 10:52:38**

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-04T23:46:42', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '17bc4894-08ea-4bc1-8d17-eba0779377ba'	System	05 Oct 2020 04:46:45
User entered 'No interference with activity (1)'	System	05 Oct 2020 04:46:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(19)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-04T23:46:43', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '17bc4894-08ea-4bc1-8d17-eba0779377ba'	System	05 Oct 2020 04:46:45
User entered '04 Oct 2020 23:46'	System	05 Oct 2020 04:46:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(19)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	04 Oct 2020 03:22:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(19)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	04 Oct 2020 03:22:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(20)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Oct 2020 03:22:52
User entered 'Day 20'	System	04 Oct 2020 03:22:52



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(20)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 03:22:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(20)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 03:22:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(21)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Oct 2020 04:46:45
User entered 'Day 21'	System	05 Oct 2020 04:46:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(21)**

**Generated On: 26 Nov 2020 10:52:38**

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-07T00:07:06', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5c03ac26-88c5-44c8-9148-b6ef22437a23'	System	07 Oct 2020 05:07:09
User entered 'None (0)'	System	07 Oct 2020 05:07:09

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(21)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-07T00:07:08', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5c03ac26-88c5-44c8-9148-b6ef22437a23'	System	07 Oct 2020 05:07:09
User entered '07 Oct 2020 00:07'	System	07 Oct 2020 05:07:09

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(21)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 04:46:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(21)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 04:46:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 02:32:30
User entered 'Day 8'	System	22 Sep 2020 02:32:30



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-23T22:00:19', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'bb552811-a7e7-4479-99a1-8ba83d9bb8e2'	System	24 Sep 2020 03:00:27
User entered 'No interference with activity (1)'	System	24 Sep 2020 03:00:27

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-23T22:00:22', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'bb552811-a7e7-4479-99a1-8ba83d9bb8e2'	System	24 Sep 2020 03:00:27
User entered '23 Sep 2020 22:00'	System	24 Sep 2020 03:00:27

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 02:32:30

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 02:32:30

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 04:20:59
User entered 'Day 9'	System	23 Sep 2020 04:20:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-24T22:32:28', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a6a13a2b-76d2-43a1-9f55-e714b8c5e121'	System	25 Sep 2020 03:32:36
User entered 'Some interference with activity (2)'	System	25 Sep 2020 03:32:36

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-24T22:32:31', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a6a13a2b-76d2-43a1-9f55-e714b8c5e121'	System	25 Sep 2020 03:32:36
User entered '24 Sep 2020 22:32'	System	25 Sep 2020 03:32:36

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 04:20:59



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 04:20:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 03:00:27
User entered 'Day 10'	System	24 Sep 2020 03:00:27

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-25T23:21:05', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'ca62fd2e-541e-49c7-b928-98059e238122'	System	26 Sep 2020 04:21:10
User entered 'Some interference with activity (2)'	System	26 Sep 2020 04:21:10

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-25T23:21:07', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'ca62fd2e-541e-49c7-b928-98059e238122'	System	26 Sep 2020 04:21:10
User entered '25 Sep 2020 23:21'	System	26 Sep 2020 04:21:10

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 03:00:27

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 03:00:27

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 03:32:36
User entered 'Day 11'	System	25 Sep 2020 03:32:36

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-26T21:32:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c43beeee-79a7-4fc4-bbee-8378f8ac8029'	System	27 Sep 2020 02:32:06
User entered 'No interference with activity (1)'	System	27 Sep 2020 02:32:06



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-26T21:32:03', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c43beeee-79a7-4fc4-bbee-8378f8ac8029'	System	27 Sep 2020 02:32:06
User entered '26 Sep 2020 21:32'	System	27 Sep 2020 02:32:06

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 03:32:36

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 03:32:36

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 04:21:10
User entered 'Day 12'	System	26 Sep 2020 04:21:10

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-27T23:52:55', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '773367c0-503c-4641-a893-c0c8dcd0cb97'	System	28 Sep 2020 04:53:00
User entered 'Some interference with activity (2)'	System	28 Sep 2020 04:53:00

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-27T23:52:57', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '773367c0-503c-4641-a893-c0c8dcd0cb97'	System	28 Sep 2020 04:53:00
User entered '27 Sep 2020 23:52'	System	28 Sep 2020 04:53:00

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 04:21:10

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 04:21:10



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	27 Sep 2020 02:32:06
User entered 'Day 13'	System	27 Sep 2020 02:32:06

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-28T21:16:17', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'dc1c60c7-a86b-433d-8e59-59c54886c8ef'	System	29 Sep 2020 02:16:21
User entered 'Some interference with activity (2)'	System	29 Sep 2020 02:16:21

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-28T21:16:19', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'dc1c60c7-a86b-433d-8e59-59c54886c8ef'	System	29 Sep 2020 02:16:21
User entered '28 Sep 2020 21:16'	System	29 Sep 2020 02:16:21

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	27 Sep 2020 02:32:06

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	27 Sep 2020 02:32:06

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 04:53:00
User entered 'Day 14'	System	28 Sep 2020 04:53:00

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-29T22:19:03', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '79b8b5f8-64a5-425f-9d27-ab830530b179'	System	30 Sep 2020 03:19:08
User entered 'No interference with activity (1)'	System	30 Sep 2020 03:19:08

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-29T22:19:05', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '79b8b5f8-64a5-425f-9d27-ab830530b179'	System	30 Sep 2020 03:19:08
User entered '29 Sep 2020 22:19'	System	30 Sep 2020 03:19:08



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 04:53:00

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 04:53:00

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 02:16:21
User entered 'Day 15'	System	29 Sep 2020 02:16:21

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-30T20:04:01', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a0564e18-9752-40a5-8849-ca47cb0dbcd3'	System	01 Oct 2020 01:04:09
User entered 'No interference with activity (1)'	System	01 Oct 2020 01:04:09

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-30T20:04:03', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a0564e18-9752-40a5-8849-ca47cb0dbcd3'	System	01 Oct 2020 01:04:09
User entered '30 Sep 2020 20:04'	System	01 Oct 2020 01:04:09

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 02:16:21

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 02:16:21

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 03:19:08
User entered 'Day 16'	System	30 Sep 2020 03:19:08



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-10-01T22:27:46', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '18584f19-6eb2-4dcf-ab56-3a307c8fad24'	System	02 Oct 2020 03:27:52
User entered 'No interference with activity (1)'	System	02 Oct 2020 03:27:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-01T22:27:48', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '18584f19-6eb2-4dcf-ab56-3a307c8fad24'	System	02 Oct 2020 03:27:52
User entered '01 Oct 2020 22:27'	System	02 Oct 2020 03:27:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 03:19:08

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 03:19:08

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(17)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 01:04:09
User entered 'Day 17'	System	01 Oct 2020 01:04:09

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(17)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 01:04:09

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(17)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 01:04:09

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(18)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 03:27:52
User entered 'Day 18'	System	02 Oct 2020 03:27:52



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(18)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-10-03T22:22:55', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '276290a8-6f97-4edb-bfe8-6d2381e62daa'	System	04 Oct 2020 03:22:58
User entered 'No interference with activity (1)'	System	04 Oct 2020 03:22:58

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(18)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-03T22:22:57', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '276290a8-6f97-4edb-bfe8-6d2381e62daa'	System	04 Oct 2020 03:22:58
User entered '03 Oct 2020 22:22'	System	04 Oct 2020 03:22:58

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(18)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 03:27:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(18)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 03:27:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(19)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Oct 2020 03:22:58
User entered 'Day 19'	System	04 Oct 2020 03:22:58

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(19)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-10-04T23:46:48', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b86f0d49-dae0-41b8-80d4-8a706729a6dc'	System	05 Oct 2020 04:46:52
User entered 'No interference with activity (1)'	System	05 Oct 2020 04:46:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(19)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-04T23:46:50', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b86f0d49-dae0-41b8-80d4-8a706729a6dc'	System	05 Oct 2020 04:46:52
User entered '04 Oct 2020 23:46'	System	05 Oct 2020 04:46:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(19)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	04 Oct 2020 03:22:58



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(19)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	04 Oct 2020 03:22:58

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(20)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Oct 2020 03:22:58
User entered 'Day 20'	System	04 Oct 2020 03:22:58

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(20)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 03:22:58

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(20)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 03:22:58

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(21)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Oct 2020 04:46:52
User entered 'Day 21'	System	05 Oct 2020 04:46:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(21)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-10-07T00:07:12', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5fe062c8-a2e2-4de4-9476-14f8930ecc57'	System	07 Oct 2020 05:07:16
User entered 'No interference with activity (1)'	System	07 Oct 2020 05:07:16

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(21)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-07T00:07:14', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5fe062c8-a2e2-4de4-9476-14f8930ecc57'	System	07 Oct 2020 05:07:16
User entered '07 Oct 2020 00:07'	System	07 Oct 2020 05:07:16

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(21)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 04:46:52



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(21)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 04:46:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(22)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 05:07:16
User entered 'Day 22'	System	07 Oct 2020 05:07:16

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(22)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-10-07T21:04:10', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2ca2eaba-f02d-4d96-a948-da14008a6d73'	System	08 Oct 2020 02:04:13
User entered 'Some interference with activity (2)'	System	08 Oct 2020 02:04:13

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(22)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-07T21:04:12', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2ca2eaba-f02d-4d96-a948-da14008a6d73'	System	08 Oct 2020 02:04:13
User entered '07 Oct 2020 21:04'	System	08 Oct 2020 02:04:13

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(22)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	07 Oct 2020 05:07:16

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(22)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 05:07:16

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(23)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 05:07:16
User entered 'Day 23'	System	07 Oct 2020 05:07:16

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(23)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 05:07:16



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(23)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 05:07:16

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(24)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 02:04:13
User entered 'Day 24'	System	08 Oct 2020 02:04:13

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(24)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-10-09T22:02:15', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0e36d7ce-aec9-46e9-87d9-f9e1f0f62988'	System	10 Oct 2020 03:02:22
User entered 'No interference with activity (1)'	System	10 Oct 2020 03:02:22

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(24)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-09T22:02:17', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '0e36d7ce-aec9-46e9-87d9-f9e1f0f62988'	System	10 Oct 2020 03:02:22
User entered '09 Oct 2020 22:02'	System	10 Oct 2020 03:02:22

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(24)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 02:04:13

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(24)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 02:04:13

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(25)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Oct 2020 03:02:22
User entered 'Day 25'	System	10 Oct 2020 03:02:22

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(25)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-10-10T22:53:50', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a4e8cd96-6891-4fb9-9950-64bf08b36b45'	System	11 Oct 2020 03:53:56
User entered 'No interference with activity (1)'	System	11 Oct 2020 03:53:56



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(25)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-10T22:53:52', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a4e8cd96-6891-4fb9-9950-64bf08b36b45'	System	11 Oct 2020 03:53:56
User entered '10 Oct 2020 22:53'	System	11 Oct 2020 03:53:56

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(25)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	10 Oct 2020 03:02:22

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(25)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	10 Oct 2020 03:02:22

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(26)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Oct 2020 03:02:22
User entered 'Day 26'	System	10 Oct 2020 03:02:22

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(26)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-10-12T00:04:03', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '10333b44-ecc3-4281-b27e-efd21c18ca1d'	System	12 Oct 2020 05:04:07
User entered 'No interference with activity (1)'	System	12 Oct 2020 05:04:07

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(26)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-12T00:04:05', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '10333b44-ecc3-4281-b27e-efd21c18ca1d'	System	12 Oct 2020 05:04:07
User entered '12 Oct 2020 00:04'	System	12 Oct 2020 05:04:07

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(26)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	10 Oct 2020 03:02:22

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(26)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	10 Oct 2020 03:02:22



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(27)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Oct 2020 03:53:56
User entered 'Day 27'	System	11 Oct 2020 03:53:56

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(27)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-10-12T22:33:28', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4362ea4b-93d8-43fd-8dfe-4a2468cd5575'	System	13 Oct 2020 03:33:33
User entered 'None (0)'	System	13 Oct 2020 03:33:33

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(27)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-12T22:33:30', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '4362ea4b-93d8-43fd-8dfe-4a2468cd5575'	System	13 Oct 2020 03:33:33
User entered '12 Oct 2020 22:33'	System	13 Oct 2020 03:33:33

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(27)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	11 Oct 2020 03:53:56

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(27)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	11 Oct 2020 03:53:56

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 02:32:30
User entered 'Day 8'	System	22 Sep 2020 02:32:30

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-23T22:00:41', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6e3b5a14-d04b-416c-b55f-88e0ba60bd11'	System	24 Sep 2020 03:00:47
User entered 'No interference with activity (1)'	System	24 Sep 2020 03:00:47

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-23T22:00:45', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6e3b5a14-d04b-416c-b55f-88e0ba60bd11'	System	24 Sep 2020 03:00:47
User entered '23 Sep 2020 22:00'	System	24 Sep 2020 03:00:47



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 02:32:30

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 02:32:30

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 04:20:59
User entered 'Day 9'	System	23 Sep 2020 04:20:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-24T22:32:36', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '95d88cb4-50f8-4fcc-8070-69f6bbe132e8'	System	25 Sep 2020 03:32:40
User entered 'No interference with activity (1)'	System	25 Sep 2020 03:32:40

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-24T22:32:38', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '95d88cb4-50f8-4fcc-8070-69f6bbe132e8'	System	25 Sep 2020 03:32:40
User entered '24 Sep 2020 22:32'	System	25 Sep 2020 03:32:40

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 04:20:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 04:20:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 03:00:47
User entered 'Day 10'	System	24 Sep 2020 03:00:47



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-25T23:21:17', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '3e6af303-1f0d-4b99-bffe-2e019e6a1821'	System	26 Sep 2020 04:21:25
User entered 'No interference with activity (1)'	System	26 Sep 2020 04:21:25

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-25T23:21:20', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '3e6af303-1f0d-4b99-bffe-2e019e6a1821'	System	26 Sep 2020 04:21:25
User entered '25 Sep 2020 23:21'	System	26 Sep 2020 04:21:25

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 03:00:47

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 03:00:47

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 03:32:40
User entered 'Day 11'	System	25 Sep 2020 03:32:40

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-26T21:32:07', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f1e2b15d-172b-4483-a1fe-285b73ba9a71'	System	27 Sep 2020 02:32:12
User entered 'No interference with activity (1)'	System	27 Sep 2020 02:32:12

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-26T21:32:10', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f1e2b15d-172b-4483-a1fe-285b73ba9a71'	System	27 Sep 2020 02:32:12
User entered '26 Sep 2020 21:32'	System	27 Sep 2020 02:32:12

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 03:32:40



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 03:32:40

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 04:21:25
User entered 'Day 12'	System	26 Sep 2020 04:21:25

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-27T23:53:03', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '025e5ebe-fa87-422a-864d-06d9c6c918a5'	System	28 Sep 2020 04:53:07
User entered 'Some interference with activity (2)'	System	28 Sep 2020 04:53:07

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-27T23:53:06', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '025e5ebe-fa87-422a-864d-06d9c6c918a5'	System	28 Sep 2020 04:53:07
User entered '27 Sep 2020 23:53'	System	28 Sep 2020 04:53:07

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 04:21:25

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 04:21:25

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	27 Sep 2020 02:32:12
User entered 'Day 13'	System	27 Sep 2020 02:32:12

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-28T21:16:23', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2955dce2-0581-45a4-b8b7-ab5a3621c203'	System	29 Sep 2020 02:16:29
User entered 'Some interference with activity (2)'	System	29 Sep 2020 02:16:29



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-28T21:16:26', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2955dce2-0581-45a4-b8b7-ab5a3621c203'	System	29 Sep 2020 02:16:29
User entered '28 Sep 2020 21:16'	System	29 Sep 2020 02:16:29

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	27 Sep 2020 02:32:12

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	27 Sep 2020 02:32:12

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 04:53:07
User entered 'Day 14'	System	28 Sep 2020 04:53:07

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-29T22:19:09', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1f50e463-04eb-457f-9804-94c5b9cb8c33'	System	30 Sep 2020 03:19:15
User entered 'Some interference with activity (2)'	System	30 Sep 2020 03:19:15

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-29T22:19:12', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1f50e463-04eb-457f-9804-94c5b9cb8c33'	System	30 Sep 2020 03:19:15
User entered '29 Sep 2020 22:19'	System	30 Sep 2020 03:19:15

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 04:53:07

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 04:53:07



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 02:16:29
User entered 'Day 15'	System	29 Sep 2020 02:16:29

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-30T20:04:08', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b409b7d8-3e6f-4ea6-8676-6bf0e6dd0b8c'	System	01 Oct 2020 01:04:11
User entered 'Some interference with activity (2)'	System	01 Oct 2020 01:04:11

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-30T20:04:09', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b409b7d8-3e6f-4ea6-8676-6bf0e6dd0b8c'	System	01 Oct 2020 01:04:11
User entered '30 Sep 2020 20:04'	System	01 Oct 2020 01:04:11

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 02:16:29

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 02:16:29

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 03:19:15
User entered 'Day 16'	System	30 Sep 2020 03:19:15

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-10-01T22:27:52', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'e8827a7d-2009-46e7-bb0d-5f1f38df87a4'	System	02 Oct 2020 03:27:56
User entered 'No interference with activity (1)'	System	02 Oct 2020 03:27:56

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-01T22:27:54', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'e8827a7d-2009-46e7-bb0d-5f1f38df87a4'	System	02 Oct 2020 03:27:56
User entered '01 Oct 2020 22:27'	System	02 Oct 2020 03:27:56



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 03:19:15

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 03:19:15

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(17)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 01:04:11
User entered 'Day 17'	System	01 Oct 2020 01:04:11

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(17)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 01:04:11

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(17)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 01:04:11

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(18)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 03:27:56
User entered 'Day 18'	System	02 Oct 2020 03:27:56

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(18)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-10-03T22:23:03', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd4dd70cf-05e6-4713-8ad8-2e5fdf232eda'	System	04 Oct 2020 03:23:07
User entered 'No interference with activity (1)'	System	04 Oct 2020 03:23:07

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(18)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-03T22:23:05', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd4dd70cf-05e6-4713-8ad8-2e5fdf232eda'	System	04 Oct 2020 03:23:07
User entered '03 Oct 2020 22:23'	System	04 Oct 2020 03:23:07



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(18)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 03:27:56

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(18)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 03:27:56

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(19)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Oct 2020 03:23:07
User entered 'Day 19'	System	04 Oct 2020 03:23:07

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(19)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-10-04T23:46:57', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '561b9f0a-c8c3-4028-a5c4-d3062ee6b262'	System	05 Oct 2020 04:46:59
User entered 'No interference with activity (1)'	System	05 Oct 2020 04:46:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(19)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-04T23:46:59', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '561b9f0a-c8c3-4028-a5c4-d3062ee6b262'	System	05 Oct 2020 04:46:59
User entered '04 Oct 2020 23:46'	System	05 Oct 2020 04:46:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(19)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	04 Oct 2020 03:23:07

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(19)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	04 Oct 2020 03:23:07

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(20)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Oct 2020 03:23:07
User entered 'Day 20'	System	04 Oct 2020 03:23:07



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(20)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 03:23:07

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(20)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 03:23:07

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(21)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Oct 2020 04:46:59
User entered 'Day 21'	System	05 Oct 2020 04:46:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(21)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-10-07T00:07:19', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5e24ebfd-c6af-4d62-8b15-85bf647026a9'	System	07 Oct 2020 05:07:22
User entered 'None (0)'	System	07 Oct 2020 05:07:22

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(21)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-07T00:07:21', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5e24ebfd-c6af-4d62-8b15-85bf647026a9'	System	07 Oct 2020 05:07:22
User entered '07 Oct 2020 00:07'	System	07 Oct 2020 05:07:22

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(21)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 04:46:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(21)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 04:46:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 04:20:59
User entered 'Day 8'	System	23 Sep 2020 04:20:59



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-23T22:00:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '8de993af-4cc6-4ff1-82a4-41188e31dc95'	System	24 Sep 2020 03:00:57
User entered 'Some interference with activity (2)'	System	24 Sep 2020 03:00:57

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-23T22:00:52', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '8de993af-4cc6-4ff1-82a4-41188e31dc95'	System	24 Sep 2020 03:00:57
User entered '23 Sep 2020 22:00'	System	24 Sep 2020 03:00:57

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	23 Sep 2020 04:20:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 04:20:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 04:20:59
User entered 'Day 9'	System	23 Sep 2020 04:20:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-24T22:32:42', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c0c6d1f7-6141-4c37-bf9e-5d7a569e1f7f'	System	25 Sep 2020 03:32:46
User entered 'Some interference with activity (2)'	System	25 Sep 2020 03:32:46

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-24T22:32:45', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c0c6d1f7-6141-4c37-bf9e-5d7a569e1f7f' User entered '24 Sep 2020 22:32'	System	25 Sep 2020 03:32:46

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 04:20:59



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 04:20:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 03:00:57
User entered 'Day 10'	System	24 Sep 2020 03:00:57

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-25T23:21:25', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b110ef58-88f9-4610-82d1-9b260ed63e39'	System	26 Sep 2020 04:21:31
User entered 'Some interference with activity (2)'	System	26 Sep 2020 04:21:31

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-25T23:21:27', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b110ef58-88f9-4610-82d1-9b260ed63e39'	System	26 Sep 2020 04:21:31
User entered '25 Sep 2020 23:21'	System	26 Sep 2020 04:21:31

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 03:00:57

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 03:00:57

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 03:32:46
User entered 'Day 11'	System	25 Sep 2020 03:32:46

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-26T21:32:28', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '434b03b3-71de-4bc3-87f1-c9dfa0507e81'	System	27 Sep 2020 02:32:36
User entered 'No interference with activity (1)'	System	27 Sep 2020 02:32:36



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-26T21:32:31', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '434b03b3-71de-4bc3-87f1-c9dfa0507e81'	System	27 Sep 2020 02:32:36
User entered '26 Sep 2020 21:32'	System	27 Sep 2020 02:32:36

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 03:32:46

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 03:32:46

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 04:21:31
User entered 'Day 12'	System	26 Sep 2020 04:21:31

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-27T23:53:10', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f71ba276-06aa-48f9-ac77-667ab2150a8d'	System	28 Sep 2020 04:53:14
User entered 'No interference with activity (1)'	System	28 Sep 2020 04:53:14

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-27T23:53:12', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f71ba276-06aa-48f9-ac77-667ab2150a8d'	System	28 Sep 2020 04:53:14
User entered '27 Sep 2020 23:53'	System	28 Sep 2020 04:53:14

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 04:21:31

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 04:21:31



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	27 Sep 2020 02:32:36
User entered 'Day 13'	System	27 Sep 2020 02:32:36

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-28T21:16:31', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9c3ad15b-4656-40e8-9de8-9557d6fded45'	System	29 Sep 2020 02:16:36
User entered 'Some interference with activity (2)'	System	29 Sep 2020 02:16:36

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-28T21:16:33', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9c3ad15b-4656-40e8-9de8-9557d6fded45'	System	29 Sep 2020 02:16:36
User entered '28 Sep 2020 21:16'	System	29 Sep 2020 02:16:36

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	27 Sep 2020 02:32:36

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	27 Sep 2020 02:32:36

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 04:53:14
User entered 'Day 14'	System	28 Sep 2020 04:53:14

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-29T22:19:16', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6da67b42-4dfc-408e-8326-1ad938c59056'	System	30 Sep 2020 03:19:19
User entered 'Some interference with activity (2)'	System	30 Sep 2020 03:19:19

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-29T22:19:17', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '6da67b42-4dfc-408e-8326-1ad938c59056'	System	30 Sep 2020 03:19:19
User entered '29 Sep 2020 22:19'	System	30 Sep 2020 03:19:19



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 04:53:14

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 04:53:14

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 02:16:36
User entered 'Day 15'	System	29 Sep 2020 02:16:36

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-09-30T20:04:13', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '59e80a18-c02d-4071-98f8-0d9c2ecb9081'	System	01 Oct 2020 01:04:18
User entered 'Some interference with activity (2)'	System	01 Oct 2020 01:04:18

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-30T20:04:15', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '59e80a18-c02d-4071-98f8-0d9c2ecb9081'	System	01 Oct 2020 01:04:18
User entered '30 Sep 2020 20:04'	System	01 Oct 2020 01:04:18

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 02:16:36

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 02:16:36

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 03:19:19
User entered 'Day 16'	System	30 Sep 2020 03:19:19



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-10-01T22:27:57', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b1afb0ab-d4df-4ccc-8f6a-5544d9e11f14'	System	02 Oct 2020 03:28:05
User entered 'No interference with activity (1)'	System	02 Oct 2020 03:28:05

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-01T22:27:59', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'b1afb0ab-d4df-4ccc-8f6a-5544d9e11f14'	System	02 Oct 2020 03:28:05
User entered '01 Oct 2020 22:27'	System	02 Oct 2020 03:28:05

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 03:19:19

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 03:19:19

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(17)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 01:04:18
User entered 'Day 17'	System	01 Oct 2020 01:04:18

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(17)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 01:04:18

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(17)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 01:04:18

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(18)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 03:28:05
User entered 'Day 18'	System	02 Oct 2020 03:28:05



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(18)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-10-03T22:23:09', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5c62a3c8-5ae8-4f8a-831d-71275dec0918'	System	04 Oct 2020 03:23:13
User entered 'Some interference with activity (2)'	System	04 Oct 2020 03:23:13

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(18)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-03T22:23:10', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5c62a3c8-5ae8-4f8a-831d-71275dec0918'	System	04 Oct 2020 03:23:13
User entered '03 Oct 2020 22:23'	System	04 Oct 2020 03:23:13

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(18)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 03:28:05

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(18)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 03:28:05

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(19)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Oct 2020 03:23:13
User entered 'Day 19'	System	04 Oct 2020 03:23:13

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(19)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-10-04T23:47:03', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1d964f56-ea06-40be-b8bd-76cce72609b1'	System	05 Oct 2020 04:47:07
User entered 'No interference with activity (1)'	System	05 Oct 2020 04:47:07

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(19)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-04T23:47:05', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '1d964f56-ea06-40be-b8bd-76cce72609b1'	System	05 Oct 2020 04:47:07
User entered '04 Oct 2020 23:47'	System	05 Oct 2020 04:47:07

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(19)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	04 Oct 2020 03:23:13



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(19)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	04 Oct 2020 03:23:13

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(20)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Oct 2020 03:23:13
User entered 'Day 20'	System	04 Oct 2020 03:23:13

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(20)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 03:23:13

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(20)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 03:23:13

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(21)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Oct 2020 04:47:07
User entered 'Day 21'	System	05 Oct 2020 04:47:07

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(21)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-10-07T00:07:28', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a62d7486-236b-4cae-b72d-4ef21db5a430'	System	07 Oct 2020 05:07:33
User entered 'None (0)'	System	07 Oct 2020 05:07:33

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(21)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-07T00:07:30', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a62d7486-236b-4cae-b72d-4ef21db5a430'	System	07 Oct 2020 05:07:33
User entered '07 Oct 2020 00:07'	System	07 Oct 2020 05:07:33

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(21)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 04:47:07



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(21)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 04:47:07

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 02:31:45
User entered 'Day 8'	System	22 Sep 2020 02:31:45

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 26 Nov 2020 10:52:38

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 (e45941109fd6dbd5)', Time: '2020-09-23T22:00:56', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '25d1fb09-5152-48ba-a192-ae35e2e15b4f'	System	24 Sep 2020 03:01:08
User entered 'No (N)'	System	24 Sep 2020 03:01:08

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-23T22:01:00', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '25d1fb09-5152-48ba-a192-ae35e2e15b4f'	System	24 Sep 2020 03:01:08
User entered '23 Sep 2020 22:01'	System	24 Sep 2020 03:01:08

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 02:31:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 02:31:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 04:20:03
User entered 'Day 9'	System	23 Sep 2020 04:20:03

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 26 Nov 2020 10:52:38

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 (e45941109fd6dbd5)', Time: '2020-09-24T22:32:49', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9793de78-67a3-4e1d-9450-3246b5b49f90'	System	25 Sep 2020 03:33:00
User entered 'No (N)'	System	25 Sep 2020 03:33:00



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-24T22:32:56', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9793de78-67a3-4e1d-9450-3246b5b49f90'	System	25 Sep 2020 03:33:00
User entered '24 Sep 2020 22:32'	System	25 Sep 2020 03:33:00

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 04:20:03

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 04:20:03

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 03:00:24
User entered 'Day 10'	System	24 Sep 2020 03:00:24

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 26 Nov 2020 10:52:38

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 (e45941109fd6dbd5)', Time: '2020-09-25T23:21:35', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd9e423f0-ff6b-491a-abc6-00a21a5b6c73'	System	26 Sep 2020 04:21:40
User entered 'No (N)'	System	26 Sep 2020 04:21:40

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-25T23:21:36', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd9e423f0-ff6b-491a-abc6-00a21a5b6c73'	System	26 Sep 2020 04:21:40
User entered '25 Sep 2020 23:21'	System	26 Sep 2020 04:21:40

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 03:00:24

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 03:00:24



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 03:32:16
User entered 'Day 11'	System	25 Sep 2020 03:32:16

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 26 Nov 2020 10:52:38

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 (e45941109fd6dbd5)', Time: '2020-09-26T21:32:36', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2508a219-44a1-4fea-bcb9-06a97436275a'	System	27 Sep 2020 02:32:43
User entered 'No (N)'	System	27 Sep 2020 02:32:43

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-26T21:32:38', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '2508a219-44a1-4fea-bcb9-06a97436275a'	System	27 Sep 2020 02:32:43
User entered '26 Sep 2020 21:32'	System	27 Sep 2020 02:32:43

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 03:32:16

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 03:32:16

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 04:20:59
User entered 'Day 12'	System	26 Sep 2020 04:20:59

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(12)

Generated On: 26 Nov 2020 10:52:38

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 (e45941109fd6dbd5)', Time: '2020-09-27T23:53:17', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a0460a82-d959-4045-b45a-01320d685485'	System	28 Sep 2020 04:53:24
User entered 'No (N)'	System	28 Sep 2020 04:53:24

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-27T23:53:20', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a0460a82-d959-4045-b45a-01320d685485'	System	28 Sep 2020 04:53:24
User entered '27 Sep 2020 23:53'	System	28 Sep 2020 04:53:24



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 04:20:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 04:20:59

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	27 Sep 2020 02:31:45
User entered 'Day 13'	System	27 Sep 2020 02:31:45

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(13)

Generated On: 26 Nov 2020 10:52:38

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 (e45941109fd6dbd5)', Time: '2020-09-28T21:16:40', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a94c3640-7ac9-4d8c-8f1a-ba78311cfbc6'	System	29 Sep 2020 02:16:49
User entered 'Yes (Y)'	System	29 Sep 2020 02:16:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-28T21:16:48', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'a94c3640-7ac9-4d8c-8f1a-ba78311cfbc6'	System	29 Sep 2020 02:16:49
User entered '28 Sep 2020 21:16'	System	29 Sep 2020 02:16:49

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	27 Sep 2020 02:31:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(13)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	27 Sep 2020 02:31:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 04:52:43
User entered 'Day 14'	System	28 Sep 2020 04:52:43



US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(14)

Generated On: 26 Nov 2020 10:52:38

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 (e45941109fd6dbd5)', Time: '2020-09-29T22:19:21', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '94437ca2-55d3-486c-82d3-30d018c929dc'	System	30 Sep 2020 03:19:25
User entered 'No (N)'	System	30 Sep 2020 03:19:25

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-29T22:19:23', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '94437ca2-55d3-486c-82d3-30d018c929dc'	System	30 Sep 2020 03:19:25
User entered '29 Sep 2020 22:19'	System	30 Sep 2020 03:19:25

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 04:52:43

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(14)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 04:52:43

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 02:15:54
User entered 'Day 15'	System	29 Sep 2020 02:15:54

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(15)

Generated On: 26 Nov 2020 10:52:38

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 (e45941109fd6dbd5)', Time: '2020-09-30T20:04:19', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '3dbe58e1-10b1-45c8-b93c-378cefbdc508'	System	01 Oct 2020 01:04:22
User entered 'No (N)'	System	01 Oct 2020 01:04:22

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-09-30T20:04:21', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '3dbe58e1-10b1-45c8-b93c-378cefbdc508'	System	01 Oct 2020 01:04:22
User entered '30 Sep 2020 20:04'	System	01 Oct 2020 01:04:22

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 02:15:54



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(15)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 02:15:54

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 03:18:52
User entered 'Day 16'	System	30 Sep 2020 03:18:52

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(16)

Generated On: 26 Nov 2020 10:52:38

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 (e45941109fd6dbd5)', Time: '2020-10-01T22:28:03', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c3646ec9-e86d-448c-977f-7f8c3aa26e5c'	System	02 Oct 2020 03:28:07
User entered 'No (N)'	System	02 Oct 2020 03:28:07

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-01T22:28:05', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c3646ec9-e86d-448c-977f-7f8c3aa26e5c'	System	02 Oct 2020 03:28:07
User entered '01 Oct 2020 22:28'	System	02 Oct 2020 03:28:07

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 03:18:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(16)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 03:18:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(17)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 01:03:52
User entered 'Day 17'	System	01 Oct 2020 01:03:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(17)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 01:03:52



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(17)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 01:03:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(18)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 03:27:45
User entered 'Day 18'	System	02 Oct 2020 03:27:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(18)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-10-03T22:23:14', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f84f0687-a171-4e7d-9c58-fb140a3fa796'	System	04 Oct 2020 03:23:19
User entered 'No (N)'	System	04 Oct 2020 03:23:19

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(18)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-03T22:23:16', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'f84f0687-a171-4e7d-9c58-fb140a3fa796'	System	04 Oct 2020 03:23:19
User entered '03 Oct 2020 22:23'	System	04 Oct 2020 03:23:19

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(18)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 03:27:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(18)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 03:27:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(19)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Oct 2020 03:22:52
User entered 'Day 19'	System	04 Oct 2020 03:22:52

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(19)

Generated On: 26 Nov 2020 10:52:38

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 (e45941109fd6dbd5)', Time: '2020-10-04T23:47:09', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '76fb7aed-4c9b-4da8-93c2-b5ff0e646128'	System	05 Oct 2020 04:47:14
User entered 'No (N)'	System	05 Oct 2020 04:47:14



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(19)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-04T23:47:12', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '76fb7aed-4c9b-4da8-93c2-b5ff0e646128'	System	05 Oct 2020 04:47:14
User entered '04 Oct 2020 23:47'	System	05 Oct 2020 04:47:14

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(19)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	04 Oct 2020 03:22:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(19)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	04 Oct 2020 03:22:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(20)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Oct 2020 03:22:52
User entered 'Day 20'	System	04 Oct 2020 03:22:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(20)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 03:22:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(20)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 03:22:52

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(21)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Oct 2020 04:46:45
User entered 'Day 21'	System	05 Oct 2020 04:46:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(21)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-10-07T00:07:33', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'faaad91e-850f-439d-8d09-f2a3a36419e9'	System	07 Oct 2020 05:07:38
User entered 'No (N)'	System	07 Oct 2020 05:07:38



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(21)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-07T00:07:35', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'faaad91e-850f-439d-8d09-f2a3a36419e9'	System	07 Oct 2020 05:07:38
User entered '07 Oct 2020 00:07'	System	07 Oct 2020 05:07:38

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(21)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 04:46:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(21)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 04:46:45

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(23)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 05:07:16
User entered 'Day 23'	System	07 Oct 2020 05:07:16

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(23)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 05:07:16

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(23)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 05:07:16

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(24)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 02:04:13
User entered 'Day 24'	System	08 Oct 2020 02:04:13

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(24)

Generated On: 26 Nov 2020 10:52:38

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 (e45941109fd6dbd5)', Time: '2020-10-09T22:02:21', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '7897f052-359b-4cca-a879-a9b2dadf20b1'	System	10 Oct 2020 03:02:30
User entered 'No (N)'	System	10 Oct 2020 03:02:30



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(24)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-09T22:02:22', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '7897f052-359b-4cca-a879-a9b2dadf20b1'	System	10 Oct 2020 03:02:30
User entered '09 Oct 2020 22:02'	System	10 Oct 2020 03:02:30

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(24)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 02:04:13

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(24)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 02:04:13

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(25)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Oct 2020 03:02:22
User entered 'Day 25'	System	10 Oct 2020 03:02:22

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(25)**

**Generated On: 26 Nov 2020 10:52:38**

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 (e45941109fd6dbd5)', Time: '2020-10-10T22:53:56', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c5eeb3bd-4fd5-4ec9-9aac-c1ab15f63f8c'	System	11 Oct 2020 03:54:00
User entered 'No (N)'	System	11 Oct 2020 03:54:00

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(25)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-10T22:53:57', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c5eeb3bd-4fd5-4ec9-9aac-c1ab15f63f8c'	System	11 Oct 2020 03:54:00
User entered '10 Oct 2020 22:53'	System	11 Oct 2020 03:54:00

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(25)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	10 Oct 2020 03:02:22

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(25)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	10 Oct 2020 03:02:22



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(26)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Oct 2020 03:02:22
User entered 'Day 26'	System	10 Oct 2020 03:02:22

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(26)

Generated On: 26 Nov 2020 10:52:38

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 (e45941109fd6dbd5)', Time: '2020-10-12T00:04:09', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'cf0b4f78-2695-446f-8b15-64aacbd6f4b9'	System	12 Oct 2020 05:04:12
User entered 'No (N)'	System	12 Oct 2020 05:04:12

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(26)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-12T00:04:11', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'cf0b4f78-2695-446f-8b15-64aacbd6f4b9'	System	12 Oct 2020 05:04:12
User entered '12 Oct 2020 00:04'	System	12 Oct 2020 05:04:12

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(26)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	10 Oct 2020 03:02:22

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(26)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	10 Oct 2020 03:02:22

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(27)**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	11 Oct 2020 03:53:56
User entered 'Day 27'	System	11 Oct 2020 03:53:56

US3272169

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(27)

Generated On: 26 Nov 2020 10:52:38

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 (e45941109fd6dbd5)', Time: '2020-10-12T22:33:34', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c28ef9b7-3357-40a2-a240-908ee319f2c4'	System	13 Oct 2020 03:33:39
User entered 'No (N)'	System	13 Oct 2020 03:33:39

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(27)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-12T22:33:36', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'c28ef9b7-3357-40a2-a240-908ee319f2c4'	System	13 Oct 2020 03:33:39
User entered '12 Oct 2020 22:33'	System	13 Oct 2020 03:33:39



**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(27)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	11 Oct 2020 03:53:56

**US3272169**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(27)**

**Generated On: 26 Nov 2020 10:52:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	11 Oct 2020 03:53:56

**US3272169**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 19:47:51

**US3272169**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 19:47:51

**US3272169**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Sep 2020 19:47:51

**US3272169**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 19:47:51

US3272169

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 19:47:53

**US3272169**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:52:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Sep 2020 19:47:53



**US3272169**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 15:26:01

**US3272169**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 15:26:01

**US3272169**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Sep 2020 15:26:01

**US3272169**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 15:26:01

**US3272169**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:52:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 15:26:09

**US3272169**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:52:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Sep 2020 15:26:09

**US3272169**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 18:34:44

**US3272169**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 18:34:44



**US3272169**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Oct 2020 18:34:44

**US3272169**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 18:34:44

**US3272169**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:52:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 18:34:55

**US3272169**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:52:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Oct 2020 18:34:55

**US3272169**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:52:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 17:40:48

**US3272169**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:52:38**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 17:40:48

US3272169

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:52:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	14 Oct 2020 17:40:48

**US3272169**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:52:38**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	14 Oct 2020 17:40:48



**US3272169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 17:13:23

**US3272169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 17:13:23

**US3272169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User entered '10:45'	(b) (4), (b) (6)	14 Oct 2020 17:13:23

**US3272169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 10:45'	System	14 Oct 2020 17:13:23

US3272169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.7' C	(b) (4), (b) (6)	14 Oct 2020 17:13:23

**US3272169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Oct 2020 17:13:23

**US3272169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 17:13:23

**US3272169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '82'	(b) (4), (b) (6)	14 Oct 2020 17:13:23



**US3272169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Oct 2020 17:13:23

US3272169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '12'	(b) (4), (b) (6)	14 Oct 2020 17:13:23

**US3272169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Oct 2020 17:13:23

**US3272169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '88'	(b) (4), (b) (6)	14 Oct 2020 17:13:23

**US3272169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Oct 2020 17:13:23

**US3272169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '62'	(b) (4), (b) (6)	14 Oct 2020 17:13:23

**US3272169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Oct 2020 17:13:23

**US3272169**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 10:52:38**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 17:13:32



US3272169

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 17:13:32

**US3272169**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:52:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 17:14:11

**US3272169**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:52:38**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 17:14:11

**US3272169**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:52:38**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:10'	(b) (4), (b) (6)	14 Oct 2020 17:14:11

**US3272169**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:52:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:10'	System	14 Oct 2020 17:14:11

US3272169

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 17:14:27

**US3272169**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:52:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Oct 2020 17:14:27

**US3272169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered 'Day 64'	System	15 Aug 2020 20:07:42



**US3272169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-10-15T21:35:04', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '715a9e23-feb4-49b5-9344-ca7a5c026a61'	System	16 Oct 2020 02:35:17
User entered 'No (N)'	System	16 Oct 2020 02:35:17

**US3272169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2020-10-15T21:35:09', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '715a9e23-feb4-49b5-9344-ca7a5c026a61'	System	16 Oct 2020 02:35:17
User entered 'No (N)'	System	16 Oct 2020 02:35:17

**US3272169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-15T21:35:16', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '715a9e23-feb4-49b5-9344-ca7a5c026a61'	System	16 Oct 2020 02:35:17
User entered '15 Oct 2020 21:35:16'	System	16 Oct 2020 02:35:17

**US3272169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered '15 Oct 2020 00:01'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered '19 Oct 2020 23:59'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered 'Day 71'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-10-22T00:59:23', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd2fee350-19b7-49d1-8518-89fe8ea4798f'	System	22 Oct 2020 05:59:43
User entered 'No (N)'	System	22 Oct 2020 05:59:43

**US3272169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2020-10-22T00:59:32', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd2fee350-19b7-49d1-8518-89fe8ea4798f'	System	22 Oct 2020 05:59:43
User entered 'No (N)'	System	22 Oct 2020 05:59:43



**US3272169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-22T00:59:38', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: 'd2fee350-19b7-49d1-8518-89fe8ea4798f'	System	22 Oct 2020 05:59:43
User entered '22 Oct 2020 00:59:38'	System	22 Oct 2020 05:59:43

**US3272169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered '22 Oct 2020 00:01'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered '26 Oct 2020 23:59'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered 'Day 78'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-10-29T22:26:58', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '99d7c90d-6422-40fd-8b4c-6c335a311e35'	System	30 Oct 2020 03:27:14
User entered 'No (N)'	System	30 Oct 2020 03:27:14

**US3272169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2020-10-29T22:26:55', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '99d7c90d-6422-40fd-8b4c-6c335a311e35'	System	30 Oct 2020 03:27:14
User entered 'No (N)'	System	30 Oct 2020 03:27:14

**US3272169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-10-29T22:27:09', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '99d7c90d-6422-40fd-8b4c-6c335a311e35'	System	30 Oct 2020 03:27:14
User entered '29 Oct 2020 22:27:09'	System	30 Oct 2020 03:27:14

**US3272169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered '29 Oct 2020 00:01'	System	15 Aug 2020 20:07:42



**US3272169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered '02 Nov 2020 23:59'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered 'Day 92'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-11-12T21:09:24', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5edb749e-a244-4847-9785-bef4b7760e94'	System	13 Nov 2020 03:10:23
User entered 'Yes (Y)'	System	13 Nov 2020 03:10:23

**US3272169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2020-11-12T21:09:30', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5edb749e-a244-4847-9785-bef4b7760e94'	System	13 Nov 2020 03:10:23
User entered 'Yes (Y)'	System	13 Nov 2020 03:10:23

**US3272169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-11-12T21:09:46', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5edb749e-a244-4847-9785-bef4b7760e94'	System	13 Nov 2020 03:10:23
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Nov 2020 03:10:23

**US3272169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-11-12T21:09:53', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5edb749e-a244-4847-9785-bef4b7760e94'	System	13 Nov 2020 03:10:23
User entered 'No (N)'	System	13 Nov 2020 03:10:23

**US3272169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-11-12T21:10:02', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5edb749e-a244-4847-9785-bef4b7760e94'	System	13 Nov 2020 03:10:23
User entered 'Yes (Y)'	System	13 Nov 2020 03:10:23

**US3272169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-11-12T21:10:04', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5edb749e-a244-4847-9785-bef4b7760e94'	System	13 Nov 2020 03:10:23
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Nov 2020 03:10:23



**US3272169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-11-12T21:10:14', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '5edb749e-a244-4847-9785-bef4b7760e94'	System	13 Nov 2020 03:10:23
User entered '12 Nov 2020 21:10:14'	System	13 Nov 2020 03:10:23

**US3272169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered '12 Nov 2020 00:01'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:07:42
User entered '16 Nov 2020 23:59'	System	15 Aug 2020 20:07:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '12 Oct 2020 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '16 Oct 2020 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '19 Oct 2020 00:01'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '23 Oct 2020 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '26 Oct 2020 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '30 Oct 2020 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '02 Nov 2020 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '06 Nov 2020 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '09 Nov 2020 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '13 Nov 2020 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-11-19T21:13:09', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9eef5d2b-8d44-4dbb-aa8a-d09ac5ee1c2d'	System	20 Nov 2020 03:13:20
User entered 'No (N)'	System	20 Nov 2020 03:13:20

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2020-11-19T21:13:14', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9eef5d2b-8d44-4dbb-aa8a-d09ac5ee1c2d'	System	20 Nov 2020 03:13:20
User entered 'No (N)'	System	20 Nov 2020 03:13:20

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-11-19T21:13:17', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '9eef5d2b-8d44-4dbb-aa8a-d09ac5ee1c2d'	System	20 Nov 2020 03:13:20
User entered '19 Nov 2020 21:13:17'	System	20 Nov 2020 03:13:20

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '16 Nov 2020 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '20 Nov 2020 23:59'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[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 (e45941109fd6dbd5)', Time: '2020-11-23T22:17:16', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '8da812ce-dd0f-4a64-af6b-aaa3a03a5d8f'	System	24 Nov 2020 04:17:30
User entered 'No (N)'	System	24 Nov 2020 04:17:30

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

Have you been exposed to someone with 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 (e45941109fd6dbd5)', Time: '2020-11-23T22:17:24', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '8da812ce-dd0f-4a64-af6b-aaa3a03a5d8f'	System	24 Nov 2020 04:17:30
User entered 'No (N)'	System	24 Nov 2020 04:17:30

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e45941109fd6dbd5)', Time: '2020-11-23T22:17:26', User OID: 'PatientReportedOutcome (US3272169)', ODM File OID: '8da812ce-dd0f-4a64-af6b-aaa3a03a5d8f'	System	24 Nov 2020 04:17:30
User entered '23 Nov 2020 22:17:26'	System	24 Nov 2020 04:17:30

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 08:38:42



**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '10 Oct 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '14 Oct 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '17 Oct 2022 00:01'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:52:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:38:42
Amendment Manager: User entered '21 Oct 2022 23:59'	System	19 Nov 2020 08:38:42

**US3272169**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 14:28:08



**US3272169**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 14:28:08

**US3272169**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	13 Nov 2020 14:28:08

**US3272169**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:52:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:28:08

**US3272169**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:52:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 14:57:13

**US3272169**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:52:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Nov 2020 14:57:13

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:52:38

[Date of Contact](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30SEP2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 06:36:12
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30SEP2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:16:17
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30SEP2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 09:31:28
User entered '28 Sep 2020'	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:03:16

**US3272169**

**Folder: Covid-19 Assessment 28 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 10:52:38**

[Time of Contact](#)

Audit	User	Time (GMT)
User entered '08:00'	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:03:16

**US3272169**

**Folder: Covid-19 Assessment 28 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 10:52:38**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 08:00'	System	28 Sep 2020 21:03:16



**US3272169**

**Folder: Covid-19 Assessment 28 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 10:52:38**

[Type of Contact](#)

Audit	User	Time (GMT)
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:03:16

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:52:38

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:03:16

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:38

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:04:47

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:38

[Date](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020'	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:04:47

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:04:47

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:38

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '100'	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:04:47

**US3272169**

**Folder: Covid-19 Assessment 28 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 26 Nov 2020 10:52:38**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	28 Sep 2020 21:04:47

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:38

[Temperature](#)

Audit	User	Time (GMT)
User entered '36.8' C	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:04:47



US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:38

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:04:47

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:38

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:04:47

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:04:47

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:04:47

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:38

Fatigue

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:04:47

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:04:47

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:38

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:04:47

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:38

[Headache](#)

Audit	User	Time (GMT)
User entered 'Severe (Severe)'	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:04:47



US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:04:47

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:04:47

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:04:47

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:04:47

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:38

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:04:47

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:38

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:04:47

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:38

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:04:47

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:52:38

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:04:47



US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:52:38

[Date of Visit](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Swab Sample dated 27Sep2020 is recorded under Illness visit in EDC, however a serum sample is also reported under Illness visit dated 28Sep2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank yo' answered with 'date is correct' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 15:38:09
User opened query 'Per GCL Lab Reconciliation: Swab Sample dated 27Sep2020 is recorded under Illness visit in EDC, however a serum sample is also reported under Illness visit dated 28Sep2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank yo' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 22:27:11
Query 'Per GCL Lab Reconciliation: Swab Sample dated 28Sep2020 is recorded under Illness visit in EDC, however a saliva sample is also reported under Illness visit dated 30Sep2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank you.	(b) (4), (b) (6)	25 Oct 2020 22:25:32
' canceled (Site from DM).		
User opened query 'Per GCL Lab Reconciliation: Swab Sample dated 28Sep2020 is recorded under Illness visit in EDC, however a saliva sample is also reported under Illness visit dated 30Sep2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank you.	(b) (4), (b) (6)	25 Oct 2020 20:57:57
' (Site from DM).		
User entered '28 Sep 2020'	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:03:35

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:52:38

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: As per the CCG v 2, please add illness folder using ADD EVENT DROP Down. Please review and update the EDC as the SARS-CoV-2 serum sample dated 28 SEP 2020 is reported under Illness Visit Day 1 in PPD Central lab. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 08:30:39
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: As per the CCG v 2, please add illness folder using ADD EVENT DROP Down. Please review and update the EDC as the SARS-CoV-2 serum sample dated 28 SEP 2020 is reported under Illness Visit Day 1 in PPD Central lab. Else clarify, thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:16:06
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: As per the CCG v 2, please add illness folder using ADD EVENT DROP Down. Please review and update the EDC as the SARS-CoV-2 serum sample dated 28 SEP 2020 is reported under Illness Visit Day 1 in PPD Central lab. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 08:54:15
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:03:35

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:52:38

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:03:35

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:52:38

[Date of Test](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020'	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:03:35

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:52:38

Type of Test Performed

Audit	User	Time (GMT)
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:03:35

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:52:38

[Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:03:35

US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:52:38

Was this diagnostic test performed at a lab other than the Study Central Lab?

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:03:35

**US3272169**

**Folder: Covid-19 Assessment 28 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 10:52:38**

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:03:35



US3272169

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:52:38

[CLIA Certified?](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	28 Sep 2020 21:03:35

**US3272169**

**Folder: Covid-19 Assessment 28 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 10:52:38**

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Sep 2020 21:03:35

**US3272169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	11 Nov 2020 15:20:43

**US3272169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 15:20:43

**US3272169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	(b) (4), (b) (6)	11 Nov 2020 15:20:43

**US3272169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	11 Nov 2020 15:20:43

**US3272169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 15:20:43

**US3272169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '2 Oct 2020'	(b) (4), (b) (6)	11 Nov 2020 15:20:43



**US3272169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	11 Nov 2020 15:20:43

**US3272169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	11 Nov 2020 15:20:43

**US3272169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 15:20:43

**US3272169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	11 Nov 2020 15:20:43

**US3272169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	11 Nov 2020 15:20:43

**US3272169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 15:20:43

**US3272169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 26 Nov 2020 10:52:38**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	11 Nov 2020 15:20:43

**US3272169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 26 Nov 2020 10:52:38**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	11 Nov 2020 15:20:43



**US3272169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 26 Nov 2020 10:52:38**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 15:20:43

**US3272169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	11 Nov 2020 15:20:43

**US3272169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	11 Nov 2020 15:20:43

**US3272169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 15:20:43

**US3272169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	11 Nov 2020 15:20:43

**US3272169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	11 Nov 2020 15:20:43

**US3272169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 15:20:43

**US3272169**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:52:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 15:16:43



**US3272169**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:52:38**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020'	(b) (4), (b) (6)	11 Nov 2020 15:16:43

**US3272169**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:52:38**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Nov 2020 15:16:43

**US3272169**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:52:38**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	11 Nov 2020 15:16:43

**US3272169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 15:17:43

**US3272169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Sep 2020'	(b) (4), (b) (6)	11 Nov 2020 15:17:43

**US3272169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User entered '15:18'	(b) (4), (b) (6)	11 Nov 2020 15:17:43

**US3272169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 15:18'	System	11 Nov 2020 15:17:43

**US3272169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '175' cm	(b) (4), (b) (6)	11 Nov 2020 15:17:43
DataPoint set to visible.	System	11 Nov 2020 15:16:43



**US3272169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '135.6' kg	(b) (4), (b) (6)	11 Nov 2020 15:17:43
DataPoint set to visible.	System	11 Nov 2020 15:16:43

US3272169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	(b) (4), (b) (6)	11 Nov 2020 15:17:43

**US3272169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Nov 2020 15:17:43

**US3272169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 15:17:43

**US3272169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '76'	(b) (4), (b) (6)	11 Nov 2020 15:17:43

**US3272169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Nov 2020 15:17:43

US3272169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '17'	(b) (4), (b) (6)	11 Nov 2020 15:17:43

**US3272169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Nov 2020 15:17:43



**US3272169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '95'	(b) (4), (b) (6)	11 Nov 2020 15:17:43

**US3272169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Nov 2020 15:17:43

US3272169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '66'	(b) (4), (b) (6)	11 Nov 2020 15:17:43

**US3272169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:52:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Nov 2020 15:17:43

**US3272169**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 10:52:38**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 15:18:06

**US3272169**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 10:52:38**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User entered '28 Sep 2020'	(b) (4), (b) (6)	11 Nov 2020 15:18:06

US3272169

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 10:52:38

Was Blood Sample Taken for Immunologic Assessment of SARS\_COV-2 Infection?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 15:18:22

**US3272169**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 26 Nov 2020 10:52:38**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020'	(b) (4), (b) (6)	11 Nov 2020 15:18:22



**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 26 Nov 2020 10:52:38**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Flege (b) (4)	06 Oct 2020 20:46:49
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:48:06

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Gastroenteritis, LLT: Gastroenteritis - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 20:49:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 20:49:27
Data point term sent to Coder	System	06 Oct 2020 20:47:55
User entered 'Gastroenteritis'	Kayla Flege (b) (4)	06 Oct 2020 20:47:28

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:47:28

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:47:28

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:47:28

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:47:28

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

**Start time (00:00-23:59)**

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:47:28

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 20:47:28



**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:47:28

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

**If not Ongoing, end date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:47:28

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:47:28

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 20:47:28

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:47:28

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:47:28

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:47:28

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:47:28



**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:47:28

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:47:28

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:47:28

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:47:28

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:47:28

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:47:28

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:47:28

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:47:28



**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:47:28

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:47:28

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:47:28

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[None](#)

Audit	User	Time (GMT)
User entered '1'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:47:28

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:47:28

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:47:28

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:47:28

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:47:28



**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:47:28

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Oct 2020 20:47:28

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Oct 2020 20:47:28

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:38

[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)	06 Oct 2020 20:51:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	06 Oct 2020 20:51:17
Data point term sent to Coder	System	06 Oct 2020 20:50:00
User entered 'Fatigue'	Kayla Flege (b) (4)	06 Oct 2020 20:49:03
	(b) (4)	

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:49:03

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note, this is a solicited event per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or confirm this is unsolicited event per investigator.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 20:46:10
Query 'Per DM CLR: Note, this is a solicited event per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or confirm this is unsolicited event per investigator.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4)	02 Nov 2020 19:51:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	02 Nov 2020 19:51:20
User opened query 'Per DM CLR: Note, this is a solicited event per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or confirm this is unsolicited event per investigator.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 06:40:18
User entered 'No (N)'	Kayla Flege (b) (4)	06 Oct 2020 20:49:03

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:49:03

US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 16SEP2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 20:46:14
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 16SEP2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4)	02 Nov 2020 19:51:49
User entered '16 Sep 2020' reason for change: Data Entry Error	(b) (4)	02 Nov 2020 19:51:38
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 16SEP2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 06:40:25
User entered '17 Sep 2020'	Kayla Flege (b) (4)	06 Oct 2020 20:49:03



US3272169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:38

Start time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Per CDM: As per CCG, Start time is required for an AE that starts within 24 hours of dosing V2 D29. Please review & update accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 15:07:43
Query 'Per CDM: As per CCG, Start time is required for an AE that starts within 24 hours of dosing V2 D29. Please review & update accordingly, else clarify.' answered with 'data not collected' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:14:26
User opened query 'Per CDM: As per CCG, Start time is required for an AE that starts within 24 hours of dosing V2 D29. Please review & update accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 16:23:05
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	03 Nov 2020 19:12:48
Query 'Data is required. Please provide.' answered with 'Unknown' (Site from System).	Kayla Flege (b) (4)	06 Oct 2020 20:49:12
User opened query 'Data is required. Please provide.' (Site from System).	System	06 Oct 2020 20:49:03
User entered empty.	Kayla Flege (b) (4)	06 Oct 2020 20:49:03

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:52:38**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 20:49:03

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:49:03

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:52:38**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	06 Oct 2020 20:49:29
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	06 Oct 2020 20:49:29
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	06 Oct 2020 20:49:03
User entered '2 Oct 2020'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:49:03

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:52:38**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	03 Nov 2020 19:12:50
Query 'Data is required. Please provide.' answered with 'Unknown' (Site from System).	Kayla Flege (b) (4)	06 Oct 2020 20:49:23
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Oct 2020 20:49:03
User entered empty.	System	06 Oct 2020 20:49:03
	Kayla Flege (b) (4)	06 Oct 2020 20:49:03
	(b) (4)	

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:52:38**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 20:49:03

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:49:03

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:49:03



**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:49:03

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:49:03

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:49:03

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:49:03

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:49:03

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:49:03

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:49:03

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:49:03



**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:49:03

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:49:03

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:49:03

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:49:03

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:49:03

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:52:38**

[None](#)

Audit	User	Time (GMT)
User entered '1'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:49:03

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:49:03

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:49:03



**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Kayla Flege (b) (4)	06 Oct 2020 20:49:29
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Kayla Flege (b) (4)	06 Oct 2020 20:49:03

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:52:38**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:49:03

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:49:03

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Oct 2020 20:49:03

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Oct 2020 20:49:03

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:38

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please review and update AE term to reflect if MUSCLE ACHES is Generalized or found on a specific body location. Please reconcile with the ConMed eCRF so there is an appropriate match' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 15:08:22
User closed query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 15:08:21
Query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' answered with 'yes subject came in for illness visit and was negative for covid' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 22:04:14
User opened query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 22:57:26
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 18:55:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 18:55:57
Data point term sent to Coder	System	30 Oct 2020 18:55:13
Query 'Per CDM: Please review and update AE term to reflect if MUSCLE ACHES is Generalized or found on a specific body location. Please reconcile with the ConMed eCRF so there is an appropriate match' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:55:05
Coding entries removed.	(b) (4), (b) (6)	30 Oct 2020 18:54:57
User entered 'generalized MUSCLE ACHES' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:54:57
User opened query 'Per CDM: Please review and update AE term to reflect if MUSCLE ACHES is Generalized or found on a specific body location. Please reconcile with the ConMed eCRF so there is an appropriate match' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 10:16:13
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 20:55:24

US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:38

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	06 Oct 2020 20:55:24
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	06 Oct 2020 20:54:09
User entered 'Muscle Aches'	Kayla Flege (b) (4)	06 Oct 2020 20:53:56
	(b) (4)	

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:53:56



US3272169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:52:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note, this is a solicited event per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or confirm this is unsolicited event per investigator.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 15:08:35
Query 'Per DM CLR: Note, this is a solicited event per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or confirm this is unsolicited event per investigator.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4)	02 Nov 2020 19:52:28
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	02 Nov 2020 19:52:23
User opened query 'Per DM CLR: Note, this is a solicited event per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or confirm this is unsolicited event per investigator.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 06:40:40
User entered 'No (N)'	Kayla Flege (b) (4)	06 Oct 2020 20:53:56

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:53:56

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:53:56

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: As per CCG, Start time is required for an AE that starts within 24 hours of dosing V2 D29. Please review & update accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 15:08:43
Query 'Per CDM: As per CCG, Start time is required for an AE that starts within 24 hours of dosing V2 D29. Please review & update accordingly, else clarify.' answered with 'data not collected' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:14:46
User opened query 'Per CDM: As per CCG, Start time is required for an AE that starts within 24 hours of dosing V2 D29. Please review & update accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 16:26:01
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 10:16:35
Query 'Data is required. Please provide.' answered with 'Unknown' (Site from System).	Kayla Flege (b) (4)	06 Oct 2020 20:54:06
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
	System	06 Oct 2020 20:53:56
User entered empty.	Kayla Flege (b) (4)	06 Oct 2020 20:53:56
	(b) (4)	

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 20:53:56

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	06 Oct 2020 20:54:13
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	06 Oct 2020 20:54:13
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	06 Oct 2020 20:53:56
User entered 'Yes (Y)'	Kayla Flege (b) (4)	06 Oct 2020 20:53:56

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
User entered '3 Oct 2020'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:53:56

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 10:16:38
Query 'Data is required. Please provide.' answered with 'Unknown' (Site from System).	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:54:18
User opened query 'Data is required. Please provide.' (Site from System).	System	06 Oct 2020 20:54:13
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:53:56



**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 20:53:56

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:53:56

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:53:56

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:53:56

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:53:56

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:53:56

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:53:56

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:53:56



**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:53:56

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:53:56

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:53:56

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:53:56

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:53:56

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:53:56

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:53:56

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:53:56



**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[None](#)

Audit	User	Time (GMT)
User entered '1'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:53:56

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:53:56

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:53:56

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:53:56

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:53:56

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 20:53:56

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Oct 2020 20:53:56

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Oct 2020 20:53:56



US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:38

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 21:08:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 21:08:18
Data point term sent to Coder	System	06 Oct 2020 21:07:27
User entered 'Headache'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 21:06:43

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 21:06:43

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note, this is a solicited event per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or confirm this is unsolicited event per investigator.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 20:51:19
Query 'Per DM CLR: Note, this is a solicited event per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or confirm this is unsolicited event per investigator.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4)	02 Nov 2020 19:53:05
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	02 Nov 2020 19:52:46
User opened query 'Per DM CLR: Note, this is a solicited event per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or confirm this is unsolicited event per investigator.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 06:41:00
User entered 'No (N)'	Kayla Flege (b) (4)	06 Oct 2020 21:06:43

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User closed query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 18:29:34
Query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' answered with 'UPDATD' (Site from Safety).	Kayla Flege (b) (4)	07 Oct 2020 18:29:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	07 Oct 2020 18:29:12
User opened query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 14:20:29
User entered 'Yes (Y)'	Kayla Flege (b) (4)	06 Oct 2020 21:06:43

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 16SEP2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 20:51:24
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 16SEP2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4)	02 Nov 2020 19:53:09
User entered '16 Sep 2020' reason for change: Data Entry Error	(b) (4)	02 Nov 2020 19:52:46
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 16SEP2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 06:41:07
User entered '17 Sep 2020'	Kayla Flege (b) (4)	06 Oct 2020 21:06:43

US3272169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:52:38

Start time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Per CDM: As per CCG, Start time is required for an AE that starts within 24 hours of dosing V2 D29. Please review & update accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 15:14:26
Query 'Per CDM: As per CCG, Start time is required for an AE that starts within 24 hours of dosing V2 D29. Please review & update accordingly, else clarify.' answered with 'data not collected' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:15:02
User opened query 'Per CDM: As per CCG, Start time is required for an AE that starts within 24 hours of dosing V2 D29. Please review & update accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 16:26:36
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 10:16:54
Query 'Data is required. Please provide.' answered with 'Unknown' (Site from System).	Kayla Flege (b) (4)	06 Oct 2020 21:07:08
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	06 Oct 2020 21:06:43
User entered empty.	Kayla Flege (b) (4)	06 Oct 2020 21:06:43
	(b) (4)	

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:52:38**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 21:06:43

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 21:06:43



**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:52:38**

**If not Ongoing, end date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered '1 Oct 2020'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 21:06:43

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:52:38**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 10:16:55
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 21:07:12
User opened query 'Data is required. Please provide.' (Site from System).	System	06 Oct 2020 21:06:43
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 21:06:43

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:52:38**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 21:06:43

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 21:06:43

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 21:06:43

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 21:06:43

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 21:06:43

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 21:06:43



**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 21:06:43

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 21:06:43

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 21:06:43

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 21:06:43

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 21:06:43

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 21:06:43

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 21:06:43

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 21:06:43



**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 21:06:43

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 21:06:43

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:52:38**

[None](#)

Audit	User	Time (GMT)
User entered 'I'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 21:06:43

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 21:06:43

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 21:06:43

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 21:06:43

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:52:38**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 21:06:43

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	06 Oct 2020 21:06:43



**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Oct 2020 21:06:43

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Oct 2020 21:06:43

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:31:17
User entered 'USA-US070-2020-mRNA-1273-P301000018'	System	16 Nov 2020 15:31:13
User entered 'New'	(b) (4), (b) (6)	16 Nov 2020 15:31:13

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:38

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Anal and rectal conditions NEC, HLT: Anal and rectal disorders NEC, PT: Rectal prolapse, LLT: Rectal prolapse - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 00:02:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 00:02:35
Data point term sent to Coder	System	14 Nov 2020 00:01:29
User entered 'rectal prolapse'	(b) (4), (b) (6) (b) (4)	14 Nov 2020 00:01:01

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Nov 2020 00:01:01

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Nov 2020 00:01:01

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Nov 2020 00:01:01

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '8 Sep 2020'	(b) (4), (b) (6)	14 Nov 2020 00:01:01



**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

**Start time (00:00-23:59)**

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Nov 2020 00:01:01

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 00:01:01

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Nov 2020 00:01:01

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm the event end date of rectal prolapse (reported as 19 Oct 2020) as the subject was discharged on 24 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 13:11:09
Query 'PV Query: Please confirm the event end date of rectal prolapse (reported as 19 Oct 2020) as the subject was discharged on 24 Oct 2020.' answered with 'updated' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	23 Nov 2020 18:41:42
User entered '8 Sep 2020' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	23 Nov 2020 18:41:16
User opened query 'PV Query: Please confirm the event end date of rectal prolapse (reported as 19 Oct 2020) as the subject was discharged on 24 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 15:32:51
User entered '19 Oct 2020'	(b) (4), (b) (6)	14 Nov 2020 00:01:01

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Nov 2020 00:01:01

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 00:01:01

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Severity](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Since the subject was hospitalized for the events, appropriate event severity grade should be grade 4. Please update the event severity as such. If the severity is to remain grade 3, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 13:11:11
Query 'PV Query: Since the subject was hospitalized for the events, appropriate event severity grade should be grade 4. Please update the event severity as such. If the severity is to remain grade 3, please clarify/explain.' answered with 'udpated' (Site from Safety).	Kayla Flege (b) (4)	23 Nov 2020 18:43:49
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	(b) (4)	23 Nov 2020 18:41:29
User opened query 'PV Query: Since the subject was hospitalized for the events, appropriate event severity grade should be grade 4. Please update the event severity as such. If the severity is to remain grade 3, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 15:33:27
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	14 Nov 2020 00:01:01

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Nov 2020 00:01:01



**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Nov 2020 00:01:01

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Nov 2020 00:01:01

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	14 Nov 2020 00:01:01

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020'	(b) (4), (b) (6)	14 Nov 2020 00:01:01

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020'	(b) (4), (b) (6)	14 Nov 2020 00:01:01

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Nov 2020 00:01:01

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Nov 2020 00:01:01

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Nov 2020 00:01:01



**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Nov 2020 00:01:01

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Nov 2020 00:01:01

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Nov 2020 00:01:01

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Nov 2020 00:01:01

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the date the subject's last dose of study medication was taken prior to the event. If the subject only received the first dose, please clarify on action taken with IP with regards to next scheduled administration.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 13:11:14
Query 'PV Query: Please provide the date the subject's last dose of study medication was taken prior to the event. If the subject only received the first dose, please clarify on action taken with IP with regards to next scheduled administration.' answered with '16 SEP 2020' (Site from Safety).	Kayla Flege (b) (4)	23 Nov 2020 18:44:19
User opened query 'PV Query: Please provide the date the subject's last dose of study medication was taken prior to the event. If the subject only received the first dose, please clarify on action taken with IP with regards to next scheduled administration.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 15:32:04
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	14 Nov 2020 00:01:01

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:38

None

Audit	User	Time (GMT)
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	23 Nov 2020 18:46:11
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	Kayla Flege (b) (4)	23 Nov 2020 18:44:35
User entered '1' reason for change: Data Entry Error	(b) (4)	23 Nov 2020 18:44:35
User entered '0'	(b) (4), (b) (6)	14 Nov 2020 00:01:01

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:38

[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. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 20:12:22
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4)	23 Nov 2020 18:45:49
User entered '0' reason for change: Data Entry Error	(b) (4)	23 Nov 2020 18:44:35
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. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 09:52:57
User entered '1'	(b) (4), (b) (6)	14 Nov 2020 00:01:01

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 18:46:11
User closed query 'Per CDM: Concomitant Procedures check box "checked" however concomitant Procedures eCRF has not been updated? Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:15:15
Query 'Per CDM: Concomitant Procedures check box "checked" however concomitant Procedures eCRF has not been updated? Please review and update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 22:04:53
User opened query 'Per CDM: Concomitant Procedures check box "checked" however concomitant Procedures eCRF has not been updated? Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 09:42:50
User entered '1'	(b) (4), (b) (6)	14 Nov 2020 00:01:01



**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	14 Nov 2020 00:01:01

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Nov 2020 00:01:01

US3272169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:52:38

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'yes covid test was done 04nov2020 and was negative' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 01:18:50
Query 'Per DM CLR: SAE Narrative = RECEIVED A ROUTINE COLONOSCOPY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 01:18:03
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 15:33:09
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 15:32:33
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 15:32:19
User opened query 'Per DM CLR: SAE Narrative = RECEIVED A ROUTINE COLONOSCOPY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 09:52:47
User entered 'patient disclosed at day 85 phone call on 13nov2020 she had a rectal prolapse that started oct08sep2020 when she received a routine colonoscopy and then had a rectal prolapse repair on 19oct2020 and was inpatient from 19oct2020 to 24oct2020 then had complications and was inpatient again from 05nov2020 to 07nov2020'	(b) (4), (b) (6)	14 Nov 2020 00:01:01

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Nov 2020 00:01:01

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Nov 2020 00:01:01

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Nov 2020 00:01:01

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:31:37
User entered	(b) (4), (b) (6)	16 Nov 2020 15:31:34
'USA-US070-2020-mRNA-1273-P301000018'		

US3272169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:38

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Anal and rectal conditions NEC, HLT: Anal and rectal disorders NEC, PT: Rectal prolapse, LLT: Rectal prolapse - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 01:32:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 01:32:02
Query 'PV Query: Was a final diagnosis for the 'rectal prolapse repair complication' identified? If so, please consider updating the event term to the (specific complication), when known.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 01:13:33
Data point term sent to Coder	System	25 Nov 2020 01:12:22
Coding entries removed.	(b) (4), (b) (6)	25 Nov 2020 01:12:16
User entered 'RECTAL PROLAPSE REPAIR COMPLICATION due to constipation' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 01:12:16
User opened query 'PV Query: Was a final diagnosis for the 'rectal prolapse repair complication' identified? If so, please consider updating the event term to the (specific complication), when known.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 15:34:02
User coded data point as SOC: Gastrointestinal disorders, HLGT: Anal and rectal conditions NEC, HLT: Anal and rectal disorders NEC, PT: Rectal prolapse, LLT: Rectal prolapse - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 01:15:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 01:15:49
Data point term sent to Coder	System	14 Nov 2020 00:02:30
User entered 'rectal prolapse repair complication'	(b) (4), (b) (6)	14 Nov 2020 00:02:25



**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Nov 2020 00:02:25

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Nov 2020 00:02:25

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Nov 2020 00:02:25

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '5 Nov 2020'	(b) (4), (b) (6)	14 Nov 2020 00:02:25

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Nov 2020 00:02:25

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 00:02:25

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Nov 2020 00:02:25

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

**If not Ongoing, end date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered '7 Nov 2020'	(b) (4), (b) (6)	14 Nov 2020 00:02:25



**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Nov 2020 00:02:25

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Nov 2020 00:02:25

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Severity](#)

Audit	User	Time (GMT)
Query 'PV Query: Since the subject was hospitalized for the events, appropriate event severity grade should be grade 4. Please update the event severity as such. If the severity is to remain grade 3, please clarify/explain.' answered with 'per investigator grade was a 3' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 01:14:14
User opened query 'PV Query: Since the subject was hospitalized for the events, appropriate event severity grade should be grade 4. Please update the event severity as such. If the severity is to remain grade 3, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 15:33:46
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	14 Nov 2020 00:02:25

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Nov 2020 00:02:25

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Nov 2020 00:02:25

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Nov 2020 00:02:25

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	14 Nov 2020 00:02:25

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '5 Nov 2020'	(b) (4), (b) (6)	14 Nov 2020 00:02:25



**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '7 Nov 2020'	(b) (4), (b) (6)	14 Nov 2020 00:02:25

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Nov 2020 00:02:25

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Nov 2020 00:02:25

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Nov 2020 00:02:25

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Nov 2020 00:02:25

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Nov 2020 00:02:25

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Nov 2020 00:02:25

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Nov 2020 00:02:25



**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	14 Nov 2020 00:02:25

US3272169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:52:38

None

Audit	User	Time (GMT)
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 01:17:44
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 09:53:13
User entered 'I'	(b) (4), (b) (6)	14 Nov 2020 00:02:25

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Nov 2020 00:02:25

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Nov 2020 00:02:25

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	14 Nov 2020 00:02:25

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Nov 2020 00:02:25

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Narrative](#)

Audit	User	Time (GMT)
User entered 'patient disclosed at day 85 phone call on 13nov2020 she had a rectal prolapse that started oct08sep2020 when she received a routine colonoscopy and then had a rectal prolapse repair on 19oct2020 and was inpatient from 19oct2020 to 24oct2020 then had complications and was inpatient again from 05nov2020 to 07nov2020'	(b) (4), (b) (6)	14 Nov 2020 00:02:25

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Nov 2020 00:02:25



**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Nov 2020 00:02:25

**US3272169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Nov 2020 00:02:25

US3272169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 26 Nov 2020 10:52:38**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:48:23

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM HYDROBROMIDE, PRODUCTSYNONYM: CELEXA [CITALOPRAM HYDROBROMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 06:35:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 06:35:17
Data point term sent to Coder	System	15 Aug 2020 20:49:22
User entered 'celexas'	(b) (4), (b) (6) (b) (4)	15 Aug 2020 20:48:58

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:48:58

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Indication](#)

Audit	User	Time (GMT)
User entered 'depression'	(b) (4), (b) (6)	15 Aug 2020 20:48:58

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	(b) (4), (b) (6)	15 Aug 2020 20:48:58

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:38

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Aug 2020 20:48:58



US3272169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:52:38**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:48:58

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	15 Aug 2020 20:48:58

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:52:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:48:58

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Aug 2020 20:48:58

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:52:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:48:58

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 16:48:57
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	15 Aug 2020 20:56:23
answered with 'confirm correct' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	15 Aug 2020 20:48:58
User entered 'un UNK 2018'	(b) (4), (b) (6)	15 Aug 2020 20:48:58

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:48:58

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:48:58



**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:52:38**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:48:58

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:48:58

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 20:48:58

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 20:48:58

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 20:48:58

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: CARIPRAZINE HYDROCHLORIDE, PRODUCTSYNONYM: VRAYLAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 20:51:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 20:51:18
Data point term sent to Coder	System	15 Aug 2020 20:50:23
User entered 'vraylar'	(b) (4), (b) (6) (b) (4)	15 Aug 2020 20:49:48

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:49:48

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Indication](#)

Audit	User	Time (GMT)
User entered 'depression'	(b) (4), (b) (6)	15 Aug 2020 20:49:48



**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1.5'	(b) (4), (b) (6)	15 Aug 2020 20:49:48

US3272169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Aug 2020 20:49:48

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:49:48

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	15 Aug 2020 20:49:48

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:52:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:49:48

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Aug 2020 20:49:48

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:52:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:49:48

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 16:49:01
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	15 Aug 2020 20:56:32
answered with 'confirm correct' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	15 Aug 2020 20:49:48
User entered 'un Jun 2020'	(b) (4), (b) (6)	15 Aug 2020 20:49:48



**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:49:48

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:49:48

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:52:38**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:49:48

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:49:48

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 20:49:48

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 20:49:48

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 20:49:48

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: SOLIFENACIN SUCCINATE, PRODUCTSYNONYM: VESICARE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 15:05:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 15:05:15
Data point term sent to Coder	System	15 Aug 2020 20:50:23
User entered 'vesicare'	(b) (4), (b) (6)	15 Aug 2020 20:50:20



**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:50:20

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Indication](#)

Audit	User	Time (GMT)
User entered 'overactive bladder'	(b) (4), (b) (6)	15 Aug 2020 20:50:20

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5'	(b) (4), (b) (6)	15 Aug 2020 20:50:20

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:38

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Aug 2020 20:50:20

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:52:38**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:50:20

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	15 Aug 2020 20:50:20

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:52:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:50:20

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Aug 2020 20:50:20



**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:52:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:50:20

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 16:49:05
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	15 Aug 2020 20:56:39
answered with 'confirm correct' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	15 Aug 2020 20:50:20
User entered 'un UNK 2019'	(b) (4), (b) (6)	15 Aug 2020 20:50:20

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:50:20

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:50:20

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:50:20

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:50:20

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 20:50:20

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 20:50:20



**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:52:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 20:50:20

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: PREGABALIN, PRODUCTSYNONYM: LYRICA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 02:04:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 02:04:18
Data point term sent to Coder	System	15 Aug 2020 20:52:26
User entered 'lyrica'	(b) (4), (b) (6) (b) (4)	15 Aug 2020 20:52:20

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:52:20

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:38

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication and clarify the type and location of the NEUROPATHY (i.e. sensory or motor). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 22:06:27
Query 'Per DM CLR: Please update the indication and clarify the type and location of the NEUROPATHY (i.e. sensory or motor). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM).	Kayla Flege (b) (4)	25 Sep 2020 19:23:38
User opened query 'Per DM CLR: Please update the indication and clarify the type and location of the NEUROPATHY (i.e. sensory or motor). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 05:25:11
User entered 'neuropathy in neck'	(b) (4), (b) (6)	15 Aug 2020 20:52:20

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	(b) (4), (b) (6)	15 Aug 2020 20:52:20

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Aug 2020 20:52:20

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:52:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:52:20

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	(b) (4), (b) (6)	15 Aug 2020 20:52:20



**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:52:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:52:20

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Aug 2020 20:52:20

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:52:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:52:20

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 16:49:09
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	15 Aug 2020 20:56:46
answered with 'confirm correct' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	15 Aug 2020 20:52:36
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	15 Aug 2020 20:52:36
User entered 'UN UNK 2014' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Aug 2020 20:52:36
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	15 Aug 2020 20:52:20
User entered 'un 2014' (non-conformant).	(b) (4), (b) (6)	15 Aug 2020 20:52:20

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:52:20

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:52:20

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:52:38**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:52:20

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:52:20



**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Aug 2020 20:52:20

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 20:52:20

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:52:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 20:52:20

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:52:38

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 09:06:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 09:06:21
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	20 Nov 2020 21:25:44 20 Nov 2020 21:25:03
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 05:02:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 05:02:47
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	26 Sep 2020 15:26:37 26 Sep 2020 15:26:08
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 06:01:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 06:01:06
Data point term sent to Coder User entered 'metoprolol er'	System (b) (4), (b) (6)	15 Aug 2020 20:54:29 15 Aug 2020 20:53:32

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:52:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:53:32

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:52:38

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the type of ARRHYTHMIA (e.g. Atrial Fibrillation, Ventricular Tachycardia, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:06:57
Query 'Per DM CLR: Please update the indication to reflect the type of ARRHYTHMIA (e.g. Atrial Fibrillation, Ventricular Tachycardia, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 21:25:09
User entered 'ARRHYTHMIA (IRREGULAR HEART BEAT) ATRIAL FIBRILLATION' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Nov 2020 21:25:03
User opened query 'Per DM CLR: Please update the indication to reflect the type of ARRHYTHMIA (e.g. Atrial Fibrillation, Ventricular Tachycardia, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 07:46:43
User closed query 'Per DM CLR: Please update the indication to reflect the type of ARRHYTHMIA. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 22:07:17
Query 'Per DM CLR: Please update the indication to reflect the type of ARRHYTHMIA. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	26 Sep 2020 15:28:39
User entered 'ARRHYTHMIA (irregular heart beat)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Sep 2020 15:26:08
User opened query 'Per DM CLR: Please update the indication to reflect the type of ARRHYTHMIA. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 05:25:41
User entered 'arrhythmia'	(b) (4), (b) (6)	15 Aug 2020 20:53:32

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:52:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '25'	(b) (4), (b) (6)	15 Aug 2020 20:53:32

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:52:38**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Aug 2020 20:53:32



**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:52:38**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:53:32

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:52:38**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	15 Aug 2020 20:53:32

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:52:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:53:32

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:52:38**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Aug 2020 20:53:32

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:52:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:53:32

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:52:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 16:49:13
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	15 Aug 2020 20:56:54
answered with 'confirm correct' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	15 Aug 2020 20:53:32
User entered 'un UNK 2018'	(b) (4), (b) (6)	15 Aug 2020 20:53:32

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:53:32

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:52:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:53:32



**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:52:38**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:53:32

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:52:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:53:32

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:52:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 20:53:32

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:52:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 20:53:32

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:52:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 20:53:32

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:52:38

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE HYDROCHLORIDE, PRODUCTSYNONYM: FLEXERIL [CYCLOBENZAPRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 16:08:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 16:08:16
Data point term sent to Coder	System	22 Aug 2020 16:06:59
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE HYDROCHLORIDE, PRODUCTSYNONYM: FLEXERIL [CYCLOBENZAPRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 16:06:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 16:06:14
Query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' canceled (Site from System).	Coder Import (b) (4) (b) (4)	22 Aug 2020 16:06:11
User opened query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	Coder Import (b) (4) (b) (4)	17 Aug 2020 09:56:18
Data point term sent to Coder	System	15 Aug 2020 20:54:31
User entered 'flexeril'	(b) (4), (b) (6) (b) (4)	15 Aug 2020 20:54:28

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:54:28

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:52:38

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication and clarify the type and location of the NEUROPATHY (i.e. sensory or motor). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 22:07:52
Query 'Per DM CLR: Please update the indication and clarify the type and location of the NEUROPATHY (i.e. sensory or motor). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'udpated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	25 Sep 2020 19:24:04
User opened query 'Per DM CLR: Please update the indication and clarify the type and location of the NEUROPATHY (i.e. sensory or motor). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 05:26:19
User entered 'neuropathy in neck'	(b) (4), (b) (6)	15 Aug 2020 20:54:28



**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	(b) (4), (b) (6)	15 Aug 2020 20:54:28

US3272169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Aug 2020 20:54:28

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:52:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:54:28

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	15 Aug 2020 20:54:28

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:52:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:54:28

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Aug 2020 20:54:28

US3272169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:52:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:54:28

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:52:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 22:08:27
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	25 Sep 2020 19:24:15
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 05:27:10
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 16:49:16
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm correct' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 20:57:01
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	15 Aug 2020 20:54:28
User entered 'un UNK 2013'	(b) (4), (b) (6)	15 Aug 2020 20:54:28



**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:54:28

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:54:28

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:52:38**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:54:28

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:54:28

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 20:54:28

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 20:54:28

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:52:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 20:54:28

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:52:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE, PRODUCTSYNONYM: PRILOSEC [OMEPRAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 20:56:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 20:56:19
Data point term sent to Coder	System	15 Aug 2020 20:55:32
User entered 'prilosec'	(b) (4), (b) (6) (b) (4)	15 Aug 2020 20:55:05



**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:55:05

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Indication](#)

Audit	User	Time (GMT)
User entered 'gastroesophageal reflux disease'	(b) (4), (b) (6)	15 Aug 2020 20:55:05

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	(b) (4), (b) (6)	15 Aug 2020 20:55:05

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:52:38

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Aug 2020 20:55:05

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:52:38**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:55:05

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	15 Aug 2020 20:55:05

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:52:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:55:05

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Aug 2020 20:55:05



**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:52:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:55:05

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:52:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 16:49:22
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	15 Aug 2020 20:57:09
answered with 'confirm correct' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	15 Aug 2020 20:55:05
User entered 'un Apr 2020'	(b) (4), (b) (6)	15 Aug 2020 20:55:05

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:55:05

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:55:05

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:52:38**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:55:05

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:55:05

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 20:55:05

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 20:55:05



**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:52:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 20:55:05

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:52:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: CETRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 20:57:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 20:57:20
Data point term sent to Coder	System	15 Aug 2020 20:56:33
User entered 'cetirizine'	(b) (4), (b) (6) (b) (4)	15 Aug 2020 20:55:42

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:52:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:55:42

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:52:38**

[Indication](#)

Audit	User	Time (GMT)
User entered 'seasonal allergies'	(b) (4), (b) (6)	15 Aug 2020 20:55:42

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:52:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	(b) (4), (b) (6)	15 Aug 2020 20:55:42

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:52:38**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Aug 2020 20:55:42

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:52:38**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:55:42

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:52:38**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	15 Aug 2020 20:55:42



**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:52:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:55:42

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:52:38**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Aug 2020 20:55:42

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:52:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:55:42

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:52:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 16:49:26
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	15 Aug 2020 20:57:16
answered with 'confirm correct' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	15 Aug 2020 20:55:42
User entered 'un Apr 2020'	(b) (4), (b) (6)	15 Aug 2020 20:55:42

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:55:42

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:52:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:55:42

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:52:38**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:55:42

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:52:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:55:42



**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:52:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 20:55:42

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:52:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 20:55:42

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:52:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 20:55:42

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:52:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: VITAMIN E NOS, PRODUCTSYNONYM: VITAMIN E [VITAMIN E NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 20:57:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 20:57:20
Data point term sent to Coder	System	15 Aug 2020 20:56:35
User entered 'vitamin e'	(b) (4), (b) (6)	15 Aug 2020 20:56:13

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:52:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:56:13

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:52:38**

[Indication](#)

Audit	User	Time (GMT)
User entered 'nutritional supplement'	(b) (4), (b) (6)	15 Aug 2020 20:56:13

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:52:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '180'	(b) (4), (b) (6)	15 Aug 2020 20:56:13

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:52:38**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Aug 2020 20:56:13



US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:52:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:56:13

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:52:38**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	(b) (4), (b) (6)	15 Aug 2020 20:56:13

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:52:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:56:13

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:52:38**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Aug 2020 20:56:13

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:52:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:56:13

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:52:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 16:49:29
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	15 Aug 2020 20:56:16
answered with 'confirm correct' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	15 Aug 2020 20:56:13
User entered 'un Jun 2020'	(b) (4), (b) (6)	15 Aug 2020 20:56:13

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 20:56:13

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:52:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 20:56:13



**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:52:38**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 20:56:13

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:52:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:56:13

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:52:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Aug 2020 20:56:13

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:52:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 20:56:13

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:52:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 20:56:13

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:52:38

[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: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 22:58:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 22:58:39
Data point term sent to Coder	System	11 Sep 2020 22:57:27
User entered 'tylenol'	(b) (4), (b) (6)	11 Sep 2020 22:56:48

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:52:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 22:56:48

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:52:38

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of INJECTION SITE PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 16:51:03
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 11:10:24
Query 'Per DM CLR: Please update the indication to reflect the location and type of INJECTION SITE PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'per protocol no ae required as this is listed in eduary' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 15:37:32
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of INJECTION SITE PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 07:38:52



US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:52:38

Indication

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4)	20 Oct 2020 22:41:33
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 21:45:29
User entered 'injection site pain'	(b) (4), (b) (6)	11 Sep 2020 22:56:48

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:52:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1000' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 00:30:01
User entered '1'	(b) (4), (b) (6)	11 Sep 2020 22:56:48

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:52:38**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 00:30:01
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	11 Sep 2020 22:56:48

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:52:38**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 22:56:48

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:52:38**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	11 Sep 2020 22:56:48

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:52:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 22:56:48

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:52:38**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Sep 2020 22:56:48

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:52:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 22:56:48



**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020'	(b) (4), (b) (6)	11 Sep 2020 22:56:48

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 22:56:48

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:52:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Oct 2020 22:41:28
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 00:30:01
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 22:56:48

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:52:38**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered '19 Aug 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Oct 2020 22:41:28
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 00:30:01
User entered '22 Aug 2020'	(b) (4), (b) (6)	11 Sep 2020 22:56:48

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:52:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 22:56:48

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:52:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 22:56:48

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:52:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 22:56:48

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:52:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 22:56:48



US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:52:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: PREDNISOLONE ACETATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 04:49:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 04:49:21
Data point term sent to Coder	System	14 Oct 2020 17:35:56
User entered 'Prednisolone acetate'	(b) (4), (b) (6)	14 Oct 2020 17:35:10

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:52:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 17:35:10

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:52:38**

[Indication](#)

Audit	User	Time (GMT)
User entered 'yag laser posterior capsulotomy (left eye'	(b) (4), (b) (6)	14 Oct 2020 17:35:10

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:52:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	14 Oct 2020 17:35:10

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:52:38**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	(b) (4), (b) (6)	14 Oct 2020 17:35:10

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:52:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'drop'	(b) (4), (b) (6)	14 Oct 2020 17:35:10

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:52:38**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'four times daily (QID)'	(b) (4), (b) (6)	14 Oct 2020 17:35:10

US3272169

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:52:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 17:35:10



**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:52:38**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	(b) (4), (b) (6)	14 Oct 2020 17:35:10

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:52:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered 'topical eye'	(b) (4), (b) (6)	14 Oct 2020 17:35:10

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '9 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 17:35:10

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:52:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 17:35:10

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:52:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 17:35:10

US3272169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:52:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 17:35:10

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:52:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 17:35:10

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:52:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	14 Oct 2020 17:35:10



**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:52:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 17:35:10

**US3272169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:52:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 17:35:10

**US3272169**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 10:52:38**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	14 Oct 2020 17:26:37
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 20:48:18

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:52:38

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 22:06:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 22:06:14
User entered '19 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Nov 2020 22:06:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	20 Nov 2020 22:05:54
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	20 Oct 2020 22:45:56
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 22:45:44
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Oct 2020 22:45:44
User entered empty; reason for change Data Entry Error	Kayla Flege (b) (4)	20 Oct 2020 22:45:44
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Oct 2020 17:27:58
User entered 'un May 2014' (non-conformant).	(b) (4), (b) (6)	14 Oct 2020 17:27:58

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:52:38

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 22:06:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 22:06:14
User entered 'rectal prolapse repair' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Nov 2020 22:06:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	20 Nov 2020 22:05:54
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	20 Oct 2020 22:45:56
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 22:45:44
User entered empty; reason for change Data Entry Error	Kayla Flege (b) (4)	20 Oct 2020 22:45:44
User entered 'Cataract surgery (left eye)'	(b) (4), (b) (6)	14 Oct 2020 17:27:58

US3272169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:52:38

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 22:06:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 22:06:14
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Nov 2020 22:06:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	20 Nov 2020 22:05:54
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	20 Oct 2020 22:45:56
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 22:45:44
User entered empty; reason for change Data Entry Error	Kayla Flege (b) (4)	20 Oct 2020 22:45:44
User entered 'Medical History (MH)'	(b) (4), (b) (6)	14 Oct 2020 17:27:58

**US3272169**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 10:52:38**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	20 Nov 2020 22:05:54
DataPoint inactivated with code reason code Data not required.	Kayla Flege (b) (4)	20 Oct 2020 22:45:56
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 17:27:58

**US3272169**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 26 Nov 2020 10:52:38**

**Procedure/Surgery date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered '8 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 17:28:37



**US3272169**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'Yag laser posterior capsulotomy (left eye)'	(b) (4), (b) (6)	14 Oct 2020 17:28:37

**US3272169**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Medical History (MH)'	(b) (4), (b) (6)	14 Oct 2020 17:28:37

**US3272169**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 26 Nov 2020 10:52:38**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 17:28:37

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'USA-US070-2020-MRNA-1273-P301000018'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'Yes (Y)'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'No (N)'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'No (N)'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'Yes (Y)'	System	16 Nov 2020 15:31:13



**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'No (N)'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'No (N)'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'No (N)'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'Adam'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'Brosz'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered '2444 W. Faidley Ave'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'Grand Island'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'NE'	System	16 Nov 2020 15:31:13



**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered '68803'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:11:23
User entered 'US'	System	16 Nov 2020 15:32:09

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Nov 2020 13:11:31
User entered '1'	System	16 Nov 2020 15:32:09

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'USA-US070-2020-MRNA-1273-P301000018'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'Yes (Y)'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'No (N)'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'No (N)'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'Yes (Y)'	System	16 Nov 2020 15:31:13



**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'No (N)'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'No (N)'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'No (N)'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'Adam'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'Brosz'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered '2444 W. Faidley Ave'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'Grand Island'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'NE'	System	16 Nov 2020 15:31:13



**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered '68803'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:11:23
User entered 'US'	System	16 Nov 2020 15:32:09

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Nov 2020 13:11:31
User entered '1'	System	16 Nov 2020 15:32:09

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form (1)**

**Generated On: 26 Nov 2020 10:52:38**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '16/Nov/2020 10:32'	System	16 Nov 2020 15:32:09

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:52:38

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:11:23
User entered 'I'	(b) (4), (b) (6)	16 Nov 2020 15:32:09

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'USA-US070-2020-MRNA-1273-P301000018'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'Yes (Y)'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'No (N)'	System	16 Nov 2020 15:31:13



**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'No (N)'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'Yes (Y)'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'No (N)'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'No (N)'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'No (N)'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'Adam'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'Brosz'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered '2444 W. Faidley Ave'	System	16 Nov 2020 15:31:13



**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'Grand Island'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered 'NE'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 15:32:03
User entered '68803'	System	16 Nov 2020 15:31:13

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:11:23
User entered 'US'	System	16 Nov 2020 15:32:09

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:52:38**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Nov 2020 13:11:31
User entered '1'	System	16 Nov 2020 15:32:09

**US3272169**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000018**

**Form: Safety Report Form (2)**

**Generated On: 26 Nov 2020 10:52:38**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '24/Nov/2020 13:11'	System	24 Nov 2020 13:11:31

US3272169

Folder: SAE USA-US070-2020-MRNA-1273-P301000018

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:52:38

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 13:11:31