

US3272085 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:51:06

All time stamps listed in this document are displayed in GMT

**US3272085**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 10:51:06**

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[Participant ID](#)

US3272085

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

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US3272085

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:06

Date of Birth (MMM yyyy)	(b) (6) 1961
Age	58
Age Units	YEARS
Age (Derived)	58
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:06

Date of Informed Consent ( <i>dd MMM yyyy</i> )	07 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:51:06

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:51:06

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:51:06

Condition	PENICILLIN ALLERGY/ ANAPHYLAXIS
Start date (dd MMM yyyy)	UN UNK 1970
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 1970
Start Year (derived)	1970
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:51:06

Condition	TYPE 2 DIABETES
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)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:51:06

Condition	OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:51:06

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:51:06

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:51:06

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

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:51:06

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:51:06

Condition	AMPLATZER CRIBRIFORM OCCLUDER DEVICE
Start date (dd MMM yyyy)	29 MAY 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)	MAY 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:51:06

Condition	PATENT FORAMEN OVALE
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="checkbox"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	29 MAY 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	MAY 2013
Stop Year (derived)	2013



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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:51:06

Condition	TRANSIENT ISCHEMIC ATTACKS
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="checkbox"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	29 MAY 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	MAY 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:51:06

Condition	INTERMITTENT CHEST WALL PAIN
Start date (dd MMM yyyy)	UN DEC 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)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:51:06

Condition	DIARRHEA
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	07 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	15:30 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 15:30
Height ( <i>xxx.x</i> )	179 cm
Weight ( <i>xxx.x</i> )	89.4 kg
BMI ( <i>xxx.x</i> )	27.90175 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

---

**Specify**

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

**No Risk Identified** False

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

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:06

What was the date of randomization? (dd MMM yyyy) 07 AUG 2020

What was the participant's randomization number? 143222

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 <input type="radio"/>
	No <input checked="" type="radio"/>
Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Severe obesity (body mass index > or = 40kg/m2)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Diabetes (Type I, Type 2, or gestational)	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Liver Disease	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 26 Nov 2020 10:51:06**

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

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)	07 AUG 2020
Time of assessment (00:00-23:59)	15:30 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 15:30
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	24 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 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 10:51:06

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)	07 AUG 2020
Time of assessment (00:00-23:59)	17:27 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 17:27
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3272085

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

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) 07 AUG 2020

What was the treatment time? (00:00-23:59) 16:51 (24 HR)

Treatment Date and Time (derived) 07 AUG 2020 16:51

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	07 AUG 2020
Collection time ( <i>00:00-23:59</i> )	15:50 (24 HR)
Collection date and time (derived)	07 AUG 2020 15:50

US3272085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:51:06

Collection date ( <i>dd MMM yyyy</i> )			7 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	15:47	7 AUG 2020 15:47
Nasopharyngeal Swab 2	No		



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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

**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 07 AUG 2020 17:25

PC Open Date & Time 07 AUG 2020 17:11

PC Close Date & Time 07 AUG 2020 19:41

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °F

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

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

PC Time Stamp	07 AUG 2020 23:08
PC Open Date & Time	07 AUG 2020 20:36
PC Close Date & Time	08 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:51:06

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**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.6 °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

08 AUG 2020 20:58

---

PC Open Date & Time

08 AUG 2020 12:00

---

PC Close Date & Time

09 AUG 2020 11:59

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US3272085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:51:06

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

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Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

09 AUG 2020 17:31

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PC Open Date & Time

09 AUG 2020 12:00

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PC Close Date & Time

10 AUG 2020 11:59

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US3272085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:51:06

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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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 22:11

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:51:06

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.6 °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

11 AUG 2020 21:09

---

PC Open Date & Time

11 AUG 2020 12:00

---

PC Close Date & Time

12 AUG 2020 11:59

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US3272085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:51:06

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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 ☒

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 12 AUG 2020 22:27

PC Open Date & Time 12 AUG 2020 12:00

PC Close Date & Time 13 AUG 2020 11:59

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US3272085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:51:06

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**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 21:02

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 17:34

PC Open Date & Time

07 AUG 2020 17:11

PC Close Date & Time

07 AUG 2020 19:41

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

**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

07 AUG 2020 23:09

PC Open Date & Time

07 AUG 2020 20:36

PC Close Date & Time

08 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:51:06

**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

08 AUG 2020 20:59

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:51:06

**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

09 AUG 2020 17:31

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:51:06

**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

10 AUG 2020 22:12

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:51:06

**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

11 AUG 2020 21:10

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:51:06

**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

12 AUG 2020 22:29

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59



US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:51:06

**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

13 AUG 2020 21:02

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

**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 ☐

US3272085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 17:35
PC Open Date & Time	07 AUG 2020 17:11
PC Close Date & Time	07 AUG 2020 19:41

US3272085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

**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 ☐

US3272085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 23:09
PC Open Date & Time	07 AUG 2020 20:36
PC Close Date & Time	08 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:51:06

**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 ☒

US3272085

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:51:06

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 20:59
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:51:06

**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 ☒



US3272085

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:51:06

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 17:32
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:51:06

**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 ☒

US3272085

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:51:06

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

US3272085

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:51:06

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 ☒

US3272085

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:51:06

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

US3272085

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:51:06

**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 ☒

US3272085

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:51:06

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 22:29
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:51:06

**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 ☒



US3272085

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:51:06

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 21:03
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 26 Nov 2020 10:51:06

<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	15 AUG 2020 00:02
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3272085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

Was Contact Attempted?

Yes ☒

No ☐

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

15 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3272085

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

Was Contact Attempted?

Yes ☒

No ☐

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

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3272085

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

Was Contact Attempted?

Yes ☒

No ☐

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

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3272085

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3272085

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

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)	04 SEP 2020
Time of assessment (00:00-23:59)	14:15 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 14:15
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 SEP 2020
Time of assessment (00:00-23:59)	15:40 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 15:40
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3272085

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 SEP 2020

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

US3272085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

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)	04 SEP 2020
What was the treatment time? (00:00-23:59)	15:09 (24 HR)
Treatment Date and Time (derived)	04 SEP 2020 15:09
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

US3272085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	4 SEP 2020
Collection time ( <i>00:00-23:59</i> )	14:31 (24 HR)
Collection date and time (derived)	4 SEP 2020 14:31

US3272085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:51:06

Collection date (dd MMM yyyy)			04 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:24	04 SEP 2020 14:24
Nasopharyngeal Swab 2	No		

US3272085

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3272085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 15:43

PC Open Date & Time

04 SEP 2020 15:29

PC Close Date & Time

04 SEP 2020 17:59

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

PC Time Stamp	05 SEP 2020 02:30
PC Open Date & Time	04 SEP 2020 18:54
PC Close Date & Time	05 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:51:06

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 21:19

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:51:06

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 21:53

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:51:06

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 00:39

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:51:06

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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

08 SEP 2020 20:27

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:51:06

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

10 SEP 2020 00:00

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:51:06

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**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

10 SEP 2020 18:35

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59



US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 15:43

PC Open Date & Time

04 SEP 2020 15:29

PC Close Date & Time

04 SEP 2020 17:59

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

**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

05 SEP 2020 02:30

PC Open Date & Time

04 SEP 2020 18:54

PC Close Date & Time

05 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:51:06

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 21:19

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:51:06

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 21:54

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:51:06

**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

08 SEP 2020 00:39

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:51:06

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 20:27

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:51:06

**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

10 SEP 2020 00:00

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:51:06

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 18:35

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59



US3272085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

**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 ☐

US3272085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 15:44
PC Open Date & Time	04 SEP 2020 15:29
PC Close Date & Time	04 SEP 2020 17:59

US3272085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

**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 ☐

US3272085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

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

No ☒

Yes ☐

PC Time stamp	05 SEP 2020 02:31
PC Open Date & Time	04 SEP 2020 18:54
PC Close Date & Time	05 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:51:06

**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 ☒

US3272085

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:51:06

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 21:20
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:51:06

**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 ☒

US3272085

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:51:06

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 21:54
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59



US3272085

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:51:06

**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 ☒

US3272085

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:51:06

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 00:40
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:51:06

**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 ☒

US3272085

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:51:06

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 20:28
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:51:06

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 ☒

US3272085

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:51:06

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 00:01
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:51:06

**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 ☒

US3272085

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:51:06

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 18:35
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59



US3272085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

Was Contact Attempted?

Yes ☒

No ☐

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

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3272085

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272085

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

Was Contact Attempted?

Yes ☒

No ☐

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

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3272085

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272085

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

Was Contact Attempted?

Yes ☒

No ☐

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

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3272085

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272085

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 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

US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	2 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	14:03 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 14:03
Temperature ( <i>xxx.x</i> )	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	74 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3272085

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 OCT 2020

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

US3272085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	2 OCT 2020
Collection time ( <i>00:00-23:59</i> )	14:14 (24 HR)
Collection date and time (derived)	2 OCT 2020 14:14

US3272085

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	07 OCT 2020 00:02:56
Patient Cloud Open Date & Time	07 OCT 2020 00:01
Patient Cloud Close Date & Time	11 OCT 2020 23:59

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	14 OCT 2020 09:29:39
Patient Cloud Open Date & Time	14 OCT 2020 00:01
Patient Cloud Close Date & Time	18 OCT 2020 23:59

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	21 OCT 2020 02:38:31
Patient Cloud Open Date & Time	21 OCT 2020 00:01
Patient Cloud Close Date & Time	25 OCT 2020 23:59

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 NOV 2020 00:07:35

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 10:03:02
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59



US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

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04 OCT 2020 00:01

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[Patient Cloud Close Date & Time](#)

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08 OCT 2020 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

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11 OCT 2020 00:01

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[Patient Cloud Close Date & Time](#)

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15 OCT 2020 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this 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>	25 OCT 2020 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 OCT 2020 23:59
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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

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01 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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05 NOV 2020 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

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08 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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12 NOV 2020 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Close Date & Time](#)

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26 NOV 2020 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

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29 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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03 DEC 2020 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Close Date & Time](#)

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10 DEC 2020 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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



US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 DEC 2020 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Close Date & Time](#)

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07 JAN 2021 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

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17 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 JAN 2021 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**TIMEPOINT**

DAY 173

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

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

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

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

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

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

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

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

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

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24 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 JAN 2021 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐ 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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Close Date & Time](#)

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11 FEB 2021 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59



US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

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21 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 FEB 2021 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

28 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Close Date & Time](#)

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11 MAR 2021 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐ 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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59



US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

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28 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 APR 2021 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐  
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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Close Date & Time](#)

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08 APR 2021 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐  
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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

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11 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 APR 2021 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐  
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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

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02 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 MAY 2021 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

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16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAY 2021 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

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23 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAY 2021 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59



US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐  
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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐  
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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Close Date & Time](#)

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01 JUL 2021 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Close Date & Time](#)

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08 JUL 2021 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59



US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

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08 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 AUG 2021 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐  
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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

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29 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 SEP 2021 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

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26 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 SEP 2021 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Close Date & Time](#)

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07 OCT 2021 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐ 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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Close Date & Time](#)

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21 OCT 2021 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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



US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐ 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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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



US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

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28 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐ 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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

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05 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 DEC 2021 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Close Date & Time](#)

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23 DEC 2021 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

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02 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 JAN 2022 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

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09 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JAN 2022 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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



US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

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23 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JAN 2022 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

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06 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 FEB 2022 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Close Date & Time](#)

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17 FEB 2022 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

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20 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 FEB 2022 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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03 MAR 2022 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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06 MAR 2022 00:01

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10 MAR 2022 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT

DAY 586

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

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

No ☐

Yes ☐

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

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10 APR 2022 00:01

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14 APR 2022 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐  
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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	24 APR 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 APR 2022 23:59
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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

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01 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 MAY 2022 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

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

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

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 MAY 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 MAY 2022 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

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

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

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

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29 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 JUN 2022 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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



US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Close Date & Time](#)

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16 JUN 2022 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

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19 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JUN 2022 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Close Date & Time](#)

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07 JUL 2022 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

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

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

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUL 2022 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59



US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2022 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
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<a href="#">Patient Cloud Open Date &amp; Time</a>	14 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2022 23:59
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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2022 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Open Date & Time](#)

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04 SEP 2022 00:01

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08 SEP 2022 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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[Patient Cloud Open Date & Time](#)

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18 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 SEP 2022 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

**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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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



US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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 ☐

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

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

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[Patient Cloud Close Date & Time](#)

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06 OCT 2022 23:59

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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:51:06

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"/>

**US3272085**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 OCT 2022 23:59

US3272085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

Was Contact Attempted?

Yes ☒

No ☐

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

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3272085

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3272085**

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

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:06**

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*

**US3272085**

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

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:06**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



US3272085

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:51:06

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

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3272085

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:51:06

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

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US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

AEID	USA-US070-2020-MRNA-1273-P30 1000006
Adverse event	WORSENING INTERMITTENT CHEST WALL PAIN NON CARDIAC
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)	07 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	9 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	10 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
v6.020 DTW (1102)	347 of 1945

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

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	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

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STATES ON 14OCT2020 THAT HE  
STARTED WITH MILD CHEST  
PAIN ON WEDNESDAY  
07OCT2020 HE WOKE UP WITH  
MILD CHEST PAIN,  
DIAPHORESIS, AND SOME  
NAUSEA. HE STATES BY  
FRIDAY, 09OCT2020 THE CHEST  
PAIN WAS WORSENING AND HE  
WENT TO THE ER. HE WAS  
THEN ADMITTED TO THE  
HOSPITAL FOR A 24 HOUR  
OBSERVATION TO R/O ACUTE  
CORONARY SYNDROME, AND  
PERICARDITIS. DIAGNOSIS  
FROM HOSPITAL WAS CHEST  
WALL PAIN. HE STATES  
CARDIAC ENZYMES WERE  
NORMAL AND HE WAS  
DISCHARGED FROM THE  
HOSPITAL ON 10OCT2020. HE  
THEN SAW HIS PCP ON  
14OCT2020 DUE TO CONTINUED  
CHEST PAIN. PCP STATES THIS  
IS INTERMITTENT CHEST WALL  
PAIN THAT IS WORSENING AND  
PATIENT WAS GIVEN A SCRIPT  
FOR HYDROCODONE/APAP  
5/325 MG AND CHOLCHICINE  
0.6MG.

---

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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US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

AEID	
Adverse event	COUGH
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)	05 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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)

350 of 1945

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

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)	



US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 26 Nov 2020 10:51:06**

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

Yes ☒

No ☐

---

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

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US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:06

Name of Medication	METFORMIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DIABETES
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 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"/>

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:06

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 2007
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"/>

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:06

Name of Medication	MELOXICAM
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	OSTEOARTHRITIS
Dose per administration	15
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"/>

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:06

	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 2010	
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"/>

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:06

Name of Medication	LOSARTAN
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	HYPERTENSION
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 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"/>

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:06

	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 2010	
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"/>

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:06

Name of Medication	PIOGLITAZONE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	TYPE 2 DIABETES
Dose per administration	30
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input 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"/>



US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:06

	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 2010	
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"/>

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:06

Name of Medication	ATORVASTATIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERCHOLESTEROLEMIA
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 type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input checked="" 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"/>

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:06

	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 2012
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)	2	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:06

Name of Medication	HYDROCHLOROTHIAZIDE
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	HYPERTENSION
Dose per administration	12.5
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"/>

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:06

	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"/>

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:06

Name of Medication	LOW DOSE ASPIRIN
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	CARDIAC PROPHYLAXIS
Dose per administration	81
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"/>

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:06

	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"/>

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:51:06

Name of Medication	BYSTOLIC
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	HYPERTENSION
Dose per administration	5
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input 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"/>



US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:51:06

	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"/>

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:06

Name of Medication	OMEPRAZOLE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	GASTROESOPHAGEAL REFLUX DISEASE
Dose per administration	40
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input checked="" 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"/>

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:06

	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	UNK 2009
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"/>

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:06

Name of Medication	COLESTIPOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DIARRHEA
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input checked="" type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input 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"/>

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:06

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:51:06

Name of Medication	HYDROCODONE/APAP
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	WORSENING INTERMITTENT CHEST WALL PAIN
Dose per administration	5/325
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input checked="" type="checkbox"/>
If dose unit is Other, specify	1-2 TABLETS MAX 10/650MG
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input checked="" type="checkbox"/>
If frequency is Other, specify	EVERY 4-6 AS NEEDED
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:51:06

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

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:51:06

Name of Medication	CHOLCHICINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	WORSENING INTERMITTENT CHEST WALL PAIN
Dose per administration	0.6
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"/>



US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:51:06

	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)	14 OCT 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"/>

US3272085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:51:06

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3272085

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:51:06

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

US3272085

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:51:06

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 ☐

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

SAEID	USA-US070-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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)	4

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:51:06

SAEID	USA-US070-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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)	4
Date of submission (Pre-filled from custom function)	15/OCT/2020 20:29
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:51:06

SAEID	USA-US070-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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)	4
Date of submission (Pre-filled from custom function)	29/OCT/2020 16:50
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

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:51:06

SAEID	USA-US070-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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)	4
Date of submission (Pre-filled from custom function)	03/NOV/2020 14:31
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:51:06

SAEID	USA-US070-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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)	4
Date of submission (Pre-filled from custom function)	20/NOV/2020 15:43
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

US3272085 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

**US3272085**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 10:51:06**

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3272085'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	07 Aug 2020 21:09:16

US3272085

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 22:13:37

US3272085

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '07 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	07 Aug 2020 21:09:17

US3272085

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	07 Aug 2020 22:13:37

**US3272085**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:06**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	07 Aug 2020 22:13:37

US3272085

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:06

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1961'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	07 Aug 2020 21:09:17



US3272085

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:06

Age

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Aug 2020 15:41:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Aug 2020 15:41:42
User closed query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	15 Aug 2020 15:41:42
User entered '58' reason for change: Data Entry Error	Ashley Bell (b) (4)	15 Aug 2020 15:41:42
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 22:13:58
User opened query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	07 Aug 2020 22:13:58
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:13:58

**US3272085**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:06**

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	15 Aug 2020 15:41:42
User entered empty.	System	07 Aug 2020 22:13:58

**US3272085**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:06**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '58'	System	07 Aug 2020 22:14:33

US3272085

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:06

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	(b) (4), (b) (6)	07 Aug 2020 22:13:58

US3272085

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:06

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	07 Aug 2020 22:13:58

US3272085

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:06

White

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	07 Aug 2020 22:13:58

US3272085

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:06

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:13:58

**US3272085**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:06**

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:13:58



US3272085

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:06

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:13:58

**US3272085**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:06**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:13:58

**US3272085**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:06**

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:13:58

US3272085

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:06

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:13:58

**US3272085**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:51:06**

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:13:58

US3272085

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:51:06

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:13:58

US3272085

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:06

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '07 Aug 2020'	(b) (4), (b) (6)	07 Aug 2020 22:14:33

**US3272085**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	07 Aug 2020 22:14:33



**US3272085**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered '2020'	System	07 Aug 2020 22:14:33

**US3272085**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:51:06**

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	(b) (4), (b) (6)	07 Aug 2020 22:14:33

US3272085

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 22:14:33

US3272085

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:06

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:14:33

US3272085

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:06

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:14:33

US3272085

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:06

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 22:14:33

US3272085

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:51:06

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	07 Aug 2020 21:09:17

**US3272085**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:51:06**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Aug 2020 22:14:43



US3272085

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:51:06

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 22:14:43

US3272085

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:51:06

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 13:02:36

US3272085

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:51:06

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: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 12:49:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 12:49:37
Data point term sent to Coder	System	10 Aug 2020 13:17:26
User entered 'Penicillin Allergy/ anaphylaxis'	(b) (4), (b) (6) (b) (4)	10 Aug 2020 13:17:09

US3272085

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'un UNK 1970'	(b) (4), (b) (6)	10 Aug 2020 13:17:09

**US3272085**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 13:17:09

US3272085

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:51:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 13:17:09

**US3272085**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 13:17:09

**US3272085**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 13:17:09



**US3272085**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered 'Jan 1970'	System	10 Aug 2020 13:17:09

**US3272085**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered '1970'	System	10 Aug 2020 13:17:09

**US3272085**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 13:17:09

**US3272085**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 13:17:09

US3272085

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:51:06

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 13:49:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 13:49:18
Data point term sent to Coder	System	11 Aug 2020 13:48:14
User entered 'type 2 diabetes'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 13:48:08

US3272085

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'UN UNK 2007'	(b) (4), (b) (6)	11 Aug 2020 13:48:08

**US3272085**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:48:08

**US3272085**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 13:48:08



**US3272085**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 13:48:08

**US3272085**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:48:08

**US3272085**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	11 Aug 2020 13:48:08

**US3272085**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered '2007'	System	11 Aug 2020 13:48:08

**US3272085**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:48:08

**US3272085**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:48:08

US3272085

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:51:06

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 22:53:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 22:53:35
Data point term sent to Coder	System	13 Nov 2020 22:53:00
Coding entries removed.	(b) (4), (b) (6)	13 Nov 2020 22:52:14
User entered 'osteoARTHRITIS' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 22:52:14
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Polyarthritis, LLT: Generalized arthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 13:50:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 13:50:13
Data point term sent to Coder	System	11 Aug 2020 13:49:17
User entered 'generalized arthritis'	(b) (4), (b) (6)	11 Aug 2020 13:48:37

**US3272085**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	(b) (4), (b) (6)	11 Aug 2020 13:48:37



**US3272085**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:51:06**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:48:37

**US3272085**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:51:06**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 13:48:37

**US3272085**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 13:48:37

**US3272085**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:51:06**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:48:37

**US3272085**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	11 Aug 2020 13:48:37

**US3272085**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered '2010'	System	11 Aug 2020 13:48:37

**US3272085**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:48:37

**US3272085**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:48:37



US3272085

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:51:06

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 13:50:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 13:50:13
Data point term sent to Coder	System	11 Aug 2020 13:49:17
User entered 'hypertension'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 13:48:53

US3272085

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	(b) (4), (b) (6)	11 Aug 2020 13:48:53

**US3272085**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:51:06**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:48:53

**US3272085**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:51:06**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 13:48:53

**US3272085**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 13:48:53

US3272085

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:51:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:48:53

**US3272085**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	11 Aug 2020 13:48:53

**US3272085**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered '2010'	System	11 Aug 2020 13:48:53



**US3272085**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:48:53

**US3272085**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:48:53

US3272085

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:51:06

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 13:51:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 13:51:17
Data point term sent to Coder	System	11 Aug 2020 13:50:18
User entered 'hypercholesterolemia'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 13:49:20

**US3272085**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered 'UN UNK 2012'	(b) (4), (b) (6)	11 Aug 2020 13:49:20

**US3272085**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:51:06**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:49:20

**US3272085**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:51:06**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 13:49:20

**US3272085**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 13:49:20

**US3272085**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:51:06**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:49:20



**US3272085**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	11 Aug 2020 13:49:20

**US3272085**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered '2012'	System	11 Aug 2020 13:49:20

**US3272085**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:49:20

**US3272085**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:49:20

US3272085

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:51:06

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Pericardial disorders, HLT: Noninfectious pericarditis, PT: Pericarditis, LLT: Pericarditis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 13:51:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 13:51:17
Data point term sent to Coder	System	11 Aug 2020 13:50:21
User entered 'pericarditis'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 13:50:11

US3272085

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'UN Jun 2019'	(b) (4), (b) (6)	11 Aug 2020 13:50:11

**US3272085**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:51:06**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:50:11

**US3272085**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:51:06**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 13:50:11



**US3272085**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered 'UN Jul 2019'	(b) (4), (b) (6)	11 Aug 2020 13:50:11

**US3272085**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:51:06**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:50:11

**US3272085**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered 'Jun 2019'	System	11 Aug 2020 13:50:11

**US3272085**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered '2019'	System	11 Aug 2020 13:50:11

**US3272085**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered 'Jul 2019'	System	11 Aug 2020 13:50:11

**US3272085**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered '2019'	System	11 Aug 2020 13:50:11

US3272085

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:51:06

[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: Gastrooesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 13:52:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 13:52:09
Data point term sent to Coder	System	11 Aug 2020 13:51:24
User entered 'gastroesophageal reflux disease'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 13:50:48

**US3272085**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered 'UN UNK 2009'	(b) (4), (b) (6)	11 Aug 2020 13:50:48



**US3272085**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:51:06**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:50:48

**US3272085**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:51:06**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 13:50:48

**US3272085**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 13:50:48

**US3272085**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:51:06**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:50:48

**US3272085**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	11 Aug 2020 13:50:48

**US3272085**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered '2009'	System	11 Aug 2020 13:50:48

**US3272085**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:50:48

**US3272085**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:50:48



US3272085

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:51:06

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Product issues, HLGT: Device issues, HLT: Device malfunction events NEC, PT: Device occlusion, LLT: Device occlusion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 10:15:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 10:15:22
Data point term sent to Coder	System	11 Aug 2020 13:52:24
User entered 'amplatzzer cribriform occluder device'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 13:51:46

US3272085

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '29 May 2013'	(b) (4), (b) (6)	11 Aug 2020 13:51:46

**US3272085**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:51:06**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:51:46

US3272085

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:51:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Ongoing is marked for a procedure. Please review and confirm to add a stop date as procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 15:09:06
Query 'Per DM CLR: Ongoing is marked for a procedure. Please review and confirm to add a stop date as procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'data correct' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 20:27:23
User opened query 'Per DM CLR: Ongoing is marked for a procedure. Please review and confirm to add a stop date as procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 08:06:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 13:51:46

**US3272085**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 13:51:46

**US3272085**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:51:06**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:51:46

**US3272085**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered 'May 2013'	System	11 Aug 2020 13:51:46

**US3272085**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered '2013'	System	11 Aug 2020 13:51:46



**US3272085**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:51:46

**US3272085**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:51:46

US3272085

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:51:06

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Cardiac and vascular disorders congenital, HLT: Cardiac septal defects congenital, PT: Atrial septal defect, LLT: Foramen ovale patent - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 13:54:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 13:54:17
Data point term sent to Coder	System	11 Aug 2020 13:53:26
User entered 'patent foramen ovale'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 13:52:58

US3272085

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'UN UNK 2011'	(b) (4), (b) (6)	11 Aug 2020 13:52:58

**US3272085**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:51:06**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:52:58

**US3272085**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:51:06**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 13:52:58

**US3272085**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered '29 May 2013'	(b) (4), (b) (6)	11 Aug 2020 13:52:58

US3272085

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:51:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:52:58



**US3272085**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered 'Jan 2011'	System	11 Aug 2020 13:52:58

**US3272085**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered '2011'	System	11 Aug 2020 13:52:58

**US3272085**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered 'May 2013'	System	11 Aug 2020 13:52:58

**US3272085**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered '2013'	System	11 Aug 2020 13:52:58

US3272085

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:51:06

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Transient cerebrovascular events, PT: Transient ischaemic attack, LLT: Transient ischemic attacks - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 13:55:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 13:55:20
Data point term sent to Coder	System	11 Aug 2020 13:54:28
User entered 'transient ischemic attacks'	(b) (4), (b) (6) (b) (4)	11 Aug 2020 13:54:01

**US3272085**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered 'UN UNK 2007'	(b) (4), (b) (6)	11 Aug 2020 13:54:01

**US3272085**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:51:06**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:54:01

**US3272085**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:51:06**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 13:54:01



US3272085

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '29 May 2013'	(b) (4), (b) (6)	11 Aug 2020 13:54:01

**US3272085**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:51:06**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:54:01

**US3272085**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	11 Aug 2020 13:54:01

**US3272085**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered '2007'	System	11 Aug 2020 13:54:01

**US3272085**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered 'May 2013'	System	11 Aug 2020 13:54:01

**US3272085**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered '2013'	System	11 Aug 2020 13:54:01

US3272085

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:51:06

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal chest pain, LLT: Chest wall pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:22:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:22:25
Data point term sent to Coder	System	15 Oct 2020 16:04:15
User entered 'Intermittent chest wall pain'	Ashley Bell (b) (4) (b) (4)	15 Oct 2020 16:03:20

US3272085

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'un Dec 2019'	Ashley Bell (b) (4)	15 Oct 2020 16:03:20



**US3272085**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:51:06**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Ashley Bell (b) (4) [REDACTED]	15 Oct 2020 16:03:20

**US3272085**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:51:06**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ashley Bell (b) (4) [REDACTED]	15 Oct 2020 16:03:20

**US3272085**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered empty.	Ashley Bell (b) (4)	15 Oct 2020 16:03:20

**US3272085**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:51:06**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Ashley Bell (b) (4) [REDACTED]	15 Oct 2020 16:03:20

**US3272085**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered 'Dec 2019'	System	15 Oct 2020 16:03:20

**US3272085**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered '2019'	System	15 Oct 2020 16:03:20

**US3272085**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 16:03:20

**US3272085**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 16:03:20



US3272085

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:51:06

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:10:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:10:15
Data point term sent to Coder	System	15 Oct 2020 16:08:22
User entered 'Diarrhea'	Ashley Bell (b) (4)	15 Oct 2020 16:07:22

**US3272085**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Ashley Bell (b) (4) [REDACTED]	15 Oct 2020 16:07:22

US3272085

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:51:06

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Ashley Bell (b) (4)	15 Oct 2020 16:07:22

US3272085

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:51:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ashley Bell (b) (4) [REDACTED]	15 Oct 2020 16:07:22

**US3272085**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered empty.	Ashley Bell (b) (4)	15 Oct 2020 16:07:22

**US3272085**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:51:06**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Ashley Bell (b) (4) [REDACTED]	15 Oct 2020 16:07:22

**US3272085**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	15 Oct 2020 16:07:22

**US3272085**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered '2015'	System	15 Oct 2020 16:07:22



**US3272085**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 16:07:22

**US3272085**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 16:07:22

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

[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)	09 Nov 2020 22:16:22
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 18:15:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 18:15:40
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 12:17:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:56:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 13:55:24

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '07 Aug 2020' reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 18:15:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:56:39
User entered '7 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 13:55:24

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '15:30' reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 18:15:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:56:39
User entered '15:30'	(b) (4), (b) (6)	11 Aug 2020 13:55:24

**US3272085**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered '07 Aug 2020 15:30'	System	25 Sep 2020 18:15:40
User entered empty.	System	15 Sep 2020 23:56:39
User entered '7 Aug 2020 15:30'	System	11 Aug 2020 13:55:24

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '179' cm reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 18:15:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:56:39
User entered '179' cm	(b) (4), (b) (6)	11 Aug 2020 13:55:24
DataPoint set to visible.	System	07 Aug 2020 22:14:43

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

Weight (xxx.x)

Audit	User	Time (GMT)
User entered '89.4' kg reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 18:15:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:56:39
User entered '89.4' kg	(b) (4), (b) (6)	11 Aug 2020 13:55:24
DataPoint set to visible.	System	07 Aug 2020 22:14:43



**US3272085**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:06**

**BMI (xxx.x)**

Audit	User	Time (GMT)
User entered '27.90175'	System	25 Sep 2020 18:15:40
User entered empty.	System	15 Sep 2020 23:56:39
User entered '27.9'	System	11 Aug 2020 13:55:24
DataPoint set to visible.	System	07 Aug 2020 22:14:43

**US3272085**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:06**

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	25 Sep 2020 18:15:40
User entered empty.	System	15 Sep 2020 23:56:39
User entered 'kg/m2'	System	11 Aug 2020 13:55:24
DataPoint set to visible.	System	07 Aug 2020 22:14:43

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

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)	28 Oct 2020 11:12:22
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 18:15:46
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 18:15:40
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 12:17:25
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 12:17:25
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)	15 Sep 2020 23:56:44
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:56:39
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 20:48:19
User entered '37' C	(b) (4), (b) (6)	11 Aug 2020 13:55:24

**US3272085**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:06**

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:56:39
User entered 'Other (Other)'	(b) (4), (b) (6)	11 Aug 2020 13:55:24

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:56:39
User entered 'temporal'	(b) (4), (b) (6)	11 Aug 2020 13:55:24

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

[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 18:15:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:56:39
User entered '67'	(b) (4), (b) (6)	11 Aug 2020 13:55:24

**US3272085**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:06**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	25 Sep 2020 18:15:40
User entered empty.	System	15 Sep 2020 23:56:39
User entered 'bpm'	System	11 Aug 2020 13:55:24

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

[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 18:15:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:56:39
User entered '24'	(b) (4), (b) (6)	11 Aug 2020 13:55:24



**US3272085**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:06**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	25 Sep 2020 18:15:40
User entered empty.	System	15 Sep 2020 23:56:39
User entered 'breaths/min'	System	11 Aug 2020 13:55:24

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

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 18:15:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:56:39
User entered '117'	(b) (4), (b) (6)	11 Aug 2020 13:55:24

**US3272085**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:06**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Sep 2020 18:15:40
User entered empty.	System	15 Sep 2020 23:56:39
User entered 'mmHg'	System	11 Aug 2020 13:55:24

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

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 18:15:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:56:39
User entered '72'	(b) (4), (b) (6)	11 Aug 2020 13:55:24

**US3272085**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:06**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Sep 2020 18:15:40
User entered empty.	System	15 Sep 2020 23:56:39
User entered 'mmHg'	System	11 Aug 2020 13:55:24

US3272085

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:06

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 13:55:31

US3272085

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 09:37:47
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		05 Sep 2020 02:15:46
User entered '7 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 13:55:31

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 13:56:06



US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

**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)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

**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)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

**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)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

**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)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

**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)	11 Aug 2020 13:56:06



US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

**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)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

**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)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

**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)	11 Aug 2020 13:56:06



US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

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)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:51:06

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 13:56:06

US3272085

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 22:15:28

US3272085

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '07 Aug 2020'	(b) (4), (b) (6)	07 Aug 2020 22:15:28

US3272085

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	07 Aug 2020 22:15:28

**US3272085**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:06**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	07 Aug 2020 22:15:28



US3272085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '07 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	07 Aug 2020 21:19:33

US3272085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:06

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 03:01:31
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:01:31
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Aug 2020 21:19:33
User entered '143222' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	07 Aug 2020 21:19:33

US3272085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	07 Aug 2020 21:19:33

US3272085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:06

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)	10 Aug 2020 12:25:36

US3272085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:25:36

US3272085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:25:36

US3272085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:06

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:25:36

US3272085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:51:06

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:25:36



US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:51:06

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 19:41:59
Query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 22:28:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 22:28:10
User opened query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 16:27:59
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:51:06

Weight

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 19:42:02
Query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 22:28:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 22:28:10
User opened query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 16:28:12
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:51:06

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 19:41:59
Query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 22:28:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 22:28:10
User opened query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 16:27:59
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:51:06

Weight

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 19:42:02
Query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 22:28:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 22:28:10
User opened query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 16:28:12
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '07 Aug 2020'	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '15:30'	(b) (4), (b) (6)	10 Aug 2020 12:28:18



**US3272085**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered '07 Aug 2020 15:30'	System	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '37.0' C	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'TEMPORAL'	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 22:47:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		18 Aug 2020 22:47:53
User entered '67' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 22:47:53
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 12:28:18
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:28:18

**US3272085**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	18 Aug 2020 22:47:53
User entered empty.	System	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 22:47:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		18 Aug 2020 22:47:53
User entered '24' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 22:47:53
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 12:28:18
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:28:18

**US3272085**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	18 Aug 2020 22:47:53
User entered empty.	System	10 Aug 2020 12:28:18



US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 22:47:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		18 Aug 2020 22:47:53
User entered '117' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 22:47:53
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 12:28:18
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Aug 2020 22:47:53
User entered empty.	System	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 22:47:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		18 Aug 2020 22:47:53
User entered '72' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 22:47:53
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 12:28:18
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Aug 2020 22:47:53
User entered empty.	System	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:51:06

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 19:41:59
Query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 22:28:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 22:28:10
User opened query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 16:27:59
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:51:06

Weight

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 19:42:02
Query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 22:28:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 22:28:10
User opened query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 16:28:12
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:28:18



US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '07 Aug 2020'	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

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 10:39:20
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).		10 Aug 2020 12:28:18
User entered '17:27'	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User entered '07 Aug 2020 17:27'	System	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.6' C	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'TEMPORAL'	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 22:47:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		18 Aug 2020 22:47:53
User entered '65' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 22:47:53
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 12:28:18
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:28:18

**US3272085**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	18 Aug 2020 22:47:53
User entered empty.	System	10 Aug 2020 12:28:18



US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 22:47:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		18 Aug 2020 22:47:53
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 22:47:53
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 12:28:18
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:28:18

**US3272085**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	18 Aug 2020 22:47:53
User entered empty.	System	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 22:47:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		18 Aug 2020 22:47:53
User entered '120' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 22:47:53
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 12:28:18
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:28:18

**US3272085**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Aug 2020 22:47:53
User entered empty.	System	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 22:47:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		18 Aug 2020 22:47:53
User entered '79' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 22:47:53
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 12:28:18
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Aug 2020 22:47:53
User entered empty.	System	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:06

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:28:56

US3272085

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:06

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '07 Aug 2020'	(b) (4), (b) (6)	10 Aug 2020 12:28:56



US3272085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	07 Aug 2020 22:16:50
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	07 Aug 2020 22:16:50
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	07 Aug 2020 22:16:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 22:16:40

US3272085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:16:40

US3272085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

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)	07 Aug 2020 22:16:40

**US3272085**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:51:06**

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	07 Aug 2020 22:16:40

US3272085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

What was the treatment date? (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '07 Aug 2020'	(b) (4), (b) (6)	07 Aug 2020 22:16:40

US3272085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '16:51'	(b) (4), (b) (6)	07 Aug 2020 22:16:40

**US3272085**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:51:06**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 16:51'	System	07 Aug 2020 22:16:40

US3272085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)' reason for change: New Information	(b) (4), (b) (6)	07 Aug 2020 22:16:50
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:16:40



US3272085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	07 Aug 2020 22:16:40

US3272085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	07 Aug 2020 22:16:40

US3272085

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:34:51

US3272085

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '07 Aug 2020'	(b) (4), (b) (6)	10 Aug 2020 12:34:51

US3272085

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:06

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '15:50' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 23:03:31
User entered '16:51'	(b) (4), (b) (6)	10 Aug 2020 12:34:51

**US3272085**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered '07 Aug 2020 15:50'	System	13 Nov 2020 23:03:31
User entered '07 Aug 2020 16:51'	System	10 Aug 2020 12:34:51

US3272085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:51:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs data is required. Please review and update accordingly' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 18:10:02
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	15 Oct 2020 18:10:00
Query 'Per CDM: Per CCGs data is required. Please review and update accordingly' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 23:29:19
User entered '7 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 23:29:01
User opened query 'Per CDM: Per CCGs data is required. Please review and update accordingly' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 12:35:42
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered with '30 MIN SIT TIME PER PROTOCOL ' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 12:38:07
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	10 Aug 2020 12:36:42
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:36:42

US3272085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:51:06

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	10 Aug 2020 12:36:42



US3272085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:51:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:36:42

**US3272085**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '15:47' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 23:03:43
User entered '15:50'	(b) (4), (b) (6)	10 Aug 2020 12:36:42

**US3272085**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered '7 Aug 2020 15:47'	System	13 Nov 2020 23:03:43
User entered '7 Aug 2020 15:50'	System	16 Sep 2020 23:29:01
User entered empty.	System	10 Aug 2020 12:36:42

US3272085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:51:06

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	10 Aug 2020 12:36:42

US3272085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:51:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 12:36:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 12:36:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 12:36:49
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 12:36:42
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:36:42

US3272085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:51:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:36:42

**US3272085**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 12:36:42

US3272085

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:38:15



**US3272085**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:06**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:38:15

**US3272085**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 22:16:40

**US3272085**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:25:30', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '15963001-991b-4039-ae19-a68c065b95fa'	System	07 Aug 2020 22:25:48
User entered 'Yes (Y)'	System	07 Aug 2020 22:25:48

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:25:36', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '15963001-991b-4039-ae19-a68c065b95fa'	System	07 Aug 2020 22:25:48
User entered '98.4'	System	07 Aug 2020 22:25:48

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:25:41', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '15963001-991b-4039-ae19-a68c065b95fa'	System	07 Aug 2020 22:25:48
User entered 'No (N)'	System	07 Aug 2020 22:25:48

**US3272085**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:25:46', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '15963001-991b-4039-ae19-a68c065b95fa'	System	07 Aug 2020 22:25:48
User entered '07 Aug 2020 17:25'	System	07 Aug 2020 22:25:48

**US3272085**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 17:11'	System	07 Aug 2020 22:16:40

**US3272085**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 19:41'	System	07 Aug 2020 22:16:40



**US3272085**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 22:16:40

**US3272085**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:08:43', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4e4c3e46-3497-49a5-aec2-e26a0ea5847f'	System	08 Aug 2020 04:09:00
User entered 'Yes (Y)'	System	08 Aug 2020 04:09:00

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:08:49', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4e4c3e46-3497-49a5-aec2-e26a0ea5847f'	System	08 Aug 2020 04:09:00
User entered '97.5'	System	08 Aug 2020 04:09:00

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:08:54', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4e4c3e46-3497-49a5-aec2-e26a0ea5847f'	System	08 Aug 2020 04:09:00
User entered 'No (N)'	System	08 Aug 2020 04:09:00

**US3272085**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:08:58', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4e4c3e46-3497-49a5-aec2-e26a0ea5847f'	System	08 Aug 2020 04:09:00
User entered '07 Aug 2020 23:08'	System	08 Aug 2020 04:09:00

**US3272085**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 20:36'	System	07 Aug 2020 22:16:40

**US3272085**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 2'	System	07 Aug 2020 22:16:40



**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:58:25', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'af075266-2b33-4d63-80bd-aa144e8a5c5b'	System	09 Aug 2020 01:58:40
User entered 'Yes (Y)'	System	09 Aug 2020 01:58:40

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:58:30', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'af075266-2b33-4d63-80bd-aa144e8a5c5b'	System	09 Aug 2020 01:58:40
User entered '97.6'	System	09 Aug 2020 01:58:40

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:58:33', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'af075266-2b33-4d63-80bd-aa144e8a5c5b'	System	09 Aug 2020 01:58:40
User entered 'No (N)'	System	09 Aug 2020 01:58:40

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:58:37', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'af075266-2b33-4d63-80bd-aa144e8a5c5b'	System	09 Aug 2020 01:58:40
User entered '08 Aug 2020 20:58'	System	09 Aug 2020 01:58:40

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 3'	System	07 Aug 2020 22:16:40

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:31:11', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '16877a62-8222-4b14-8ab8-277cbda86d9'	System	09 Aug 2020 22:31:28
User entered 'Yes (Y)'	System	09 Aug 2020 22:31:28



US3272085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:51:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:31:18', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '16877a62-8222-4b14-8ab8-277cbda86d9'	System	09 Aug 2020 22:31:28
User entered '97.9'	System	09 Aug 2020 22:31:28

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:31:21', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '16877a62-8222-4b14-8ab8-277cbda86d9'	System	09 Aug 2020 22:31:28
User entered 'No (N)'	System	09 Aug 2020 22:31:28

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:31:26', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '16877a62-8222-4b14-8ab8-277cbda86d9'	System	09 Aug 2020 22:31:28
User entered '09 Aug 2020 17:31'	System	09 Aug 2020 22:31:28

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 4'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:51:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:11:16', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fb249ca0-f5c4-4020-bb23-9a030caefb5e'	System	11 Aug 2020 03:11:31
User entered 'Yes (Y)'	System	11 Aug 2020 03:11:31

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:51:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:11:21', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fb249ca0-f5c4-4020-bb23-9a030caefb5e'	System	11 Aug 2020 03:11:31
User entered '97.5'	System	11 Aug 2020 03:11:31



US3272085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:11:24', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fb249ca0-f5c4-4020-bb23-9a030caefb5e'	System	11 Aug 2020 03:11:31
User entered 'No (N)'	System	11 Aug 2020 03:11:31

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:11:27', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fb249ca0-f5c4-4020-bb23-9a030caefb5e'	System	11 Aug 2020 03:11:31
User entered '10 Aug 2020 22:11'	System	11 Aug 2020 03:11:31

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 5'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:51:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:09:42', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'b396062a-ed72-4f83-9b86-272d58fcbde3'	System	12 Aug 2020 03:09:59
User entered 'Yes (Y)'	System	12 Aug 2020 03:09:59

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:51:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:09:48', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'b396062a-ed72-4f83-9b86-272d58fcbde3'	System	12 Aug 2020 03:09:59
User entered '97.6'	System	12 Aug 2020 03:09:59

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:09:51', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'b396062a-ed72-4f83-9b86-272d58fcbde3'	System	12 Aug 2020 03:09:59
User entered 'No (N)'	System	12 Aug 2020 03:09:59



**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:09:55', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'b396062a-ed72-4f83-9b86-272d58fcbde3'	System	12 Aug 2020 03:09:59
User entered '11 Aug 2020 21:09'	System	12 Aug 2020 03:09:59

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 6'	System	07 Aug 2020 22:16:40

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-12T22:27:31', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '42c96675-3505-4d4e-ac7f-54bed42d9b26'	System	13 Aug 2020 03:27:47
User entered 'No (N)'	System	13 Aug 2020 03:27:47

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-12T22:27:35', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '42c96675-3505-4d4e-ac7f-54bed42d9b26'	System	13 Aug 2020 03:27:47
User entered 'No (N)'	System	13 Aug 2020 03:27:47

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-12T22:27:44', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '42c96675-3505-4d4e-ac7f-54bed42d9b26'	System	13 Aug 2020 03:27:47
User entered '12 Aug 2020 22:27'	System	13 Aug 2020 03:27:47

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 22:16:40



**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 7'	System	07 Aug 2020 22:16:40

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:01:58', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '9462ab27-75a7-4f08-949c-9c78da8d5d5c'	System	14 Aug 2020 02:02:14
User entered 'Yes (Y)'	System	14 Aug 2020 02:02:14

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:51:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:02:04', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '9462ab27-75a7-4f08-949c-9c78da8d5d5c'	System	14 Aug 2020 02:02:14
User entered '97.8'	System	14 Aug 2020 02:02:14

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:02:08', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '9462ab27-75a7-4f08-949c-9c78da8d5d5c'	System	14 Aug 2020 02:02:14
User entered 'No (N)'	System	14 Aug 2020 02:02:14

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:02:11', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '9462ab27-75a7-4f08-949c-9c78da8d5d5c'	System	14 Aug 2020 02:02:14
User entered '13 Aug 2020 21:02'	System	14 Aug 2020 02:02:14

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 22:16:40



**US3272085**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 22:16:40

**US3272085**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

[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 (a5a7983321c3e006)', Time: '2020-08-07T17:34:22', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'baa18a7d-a0a9-4e48-9fc1-3fa2f51583b1'	System	07 Aug 2020 22:35:01
User entered 'None (1)'	System	07 Aug 2020 22:35:01

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:34:30', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'baa18a7d-a0a9-4e48-9fc1-3fa2f51583b1'	System	07 Aug 2020 22:35:01
User entered 'No (N)'	System	07 Aug 2020 22:35:01

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:34:41', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'baa18a7d-a0a9-4e48-9fc1-3fa2f51583b1'	System	07 Aug 2020 22:35:01
User entered 'No (N)'	System	07 Aug 2020 22:35:01

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-08-07T17:34:48', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'baa18a7d-a0a9-4e48-9fc1-3fa2f51583b1'	System	07 Aug 2020 22:35:01
User entered 'None (1)'	System	07 Aug 2020 22:35:01

**US3272085**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:34:56', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'baa18a7d-a0a9-4e48-9fc1-3fa2f51583b1'	System	07 Aug 2020 22:35:01
User entered '07 Aug 2020 17:34'	System	07 Aug 2020 22:35:01

**US3272085**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 17:11'	System	07 Aug 2020 22:16:40

**US3272085**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 19:41'	System	07 Aug 2020 22:16:40



**US3272085**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 22:16:40

**US3272085**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

[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 (a5a7983321c3e006)', Time: '2020-08-07T23:09:06', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '399b97d9-0310-462a-968c-221bc0c5e0af'	System	08 Aug 2020 04:09:31
User entered 'None (1)'	System	08 Aug 2020 04:09:31

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:09:10', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '399b97d9-0310-462a-968c-221bc0c5e0af'	System	08 Aug 2020 04:09:31
User entered 'No (N)'	System	08 Aug 2020 04:09:31

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:09:13', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '399b97d9-0310-462a-968c-221bc0c5e0af'	System	08 Aug 2020 04:09:31
User entered 'No (N)'	System	08 Aug 2020 04:09:31

**US3272085**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

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 (a5a7983321c3e006)', Time: '2020-08-07T23:09:22', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '399b97d9-0310-462a-968c-221bc0c5e0af'	System	08 Aug 2020 04:09:31
User entered 'None (1)'	System	08 Aug 2020 04:09:31

**US3272085**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:09:26', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '399b97d9-0310-462a-968c-221bc0c5e0af'	System	08 Aug 2020 04:09:31
User entered '07 Aug 2020 23:09'	System	08 Aug 2020 04:09:31

**US3272085**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 20:36'	System	07 Aug 2020 22:16:40

**US3272085**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 22:16:40



**US3272085**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 2'	System	07 Aug 2020 22:16:40

**US3272085**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:06**

[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 (a5a7983321c3e006)', Time: '2020-08-08T20:58:42', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '3410980a-2066-46a7-abb7-6c92ab7973a9'	System	09 Aug 2020 01:59:04
User entered 'None (1)'	System	09 Aug 2020 01:59:04

**US3272085**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:58:45', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '3410980a-2066-46a7-abb7-6c92ab7973a9'	System	09 Aug 2020 01:59:04
User entered 'No (N)'	System	09 Aug 2020 01:59:04

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:58:53', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '3410980a-2066-46a7-abb7-6c92ab7973a9'	System	09 Aug 2020 01:59:04
User entered 'No (N)'	System	09 Aug 2020 01:59:04

**US3272085**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:06**

[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 (a5a7983321c3e006)', Time: '2020-08-08T20:58:59', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '3410980a-2066-46a7-abb7-6c92ab7973a9'	System	09 Aug 2020 01:59:04
User entered 'None (1)'	System	09 Aug 2020 01:59:04

**US3272085**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:59:02', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '3410980a-2066-46a7-abb7-6c92ab7973a9'	System	09 Aug 2020 01:59:04
User entered '08 Aug 2020 20:59'	System	09 Aug 2020 01:59:04

**US3272085**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

**US3272085**

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

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 22:16:40



**US3272085**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 3'	System	07 Aug 2020 22:16:40

**US3272085**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:06**

[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 (a5a7983321c3e006)', Time: '2020-08-09T17:31:30', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '964bfa99-b182-440f-9d60-73931be580db'	System	09 Aug 2020 22:31:45
User entered 'None (1)'	System	09 Aug 2020 22:31:45

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:51:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:31:33', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '964bfa99-b182-440f-9d60-73931be580db'	System	09 Aug 2020 22:31:45
User entered 'No (N)'	System	09 Aug 2020 22:31:45

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:31:36', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '964bfa99-b182-440f-9d60-73931be580db'	System	09 Aug 2020 22:31:45
User entered 'No (N)'	System	09 Aug 2020 22:31:45

**US3272085**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:06**

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 (a5a7983321c3e006)', Time: '2020-08-09T17:31:39', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '964bfa99-b182-440f-9d60-73931be580db'	System	09 Aug 2020 22:31:45
User entered 'None (1)'	System	09 Aug 2020 22:31:45

**US3272085**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:31:42', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '964bfa99-b182-440f-9d60-73931be580db'	System	09 Aug 2020 22:31:45
User entered '09 Aug 2020 17:31'	System	09 Aug 2020 22:31:45

**US3272085**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

**US3272085**

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

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 22:16:40



**US3272085**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 4'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-08-10T22:11:33', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2ffd53e8-ad44-4f7e-964f-80c5badd7761'	System	11 Aug 2020 03:12:10
User entered 'None (1)'	System	11 Aug 2020 03:12:10

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:51:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:11:36', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2ffd53e8-ad44-4f7e-964f-80c5badd7761'	System	11 Aug 2020 03:12:10
User entered 'No (N)'	System	11 Aug 2020 03:12:10

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:11:53', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2ffd53e8-ad44-4f7e-964f-80c5badd7761'	System	11 Aug 2020 03:12:10
User entered 'No (N)'	System	11 Aug 2020 03:12:10

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-08-10T22:12:03', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2ffd53e8-ad44-4f7e-964f-80c5badd7761'	System	11 Aug 2020 03:12:10
User entered 'None (1)'	System	11 Aug 2020 03:12:10

**US3272085**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:12:06', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2ffd53e8-ad44-4f7e-964f-80c5badd7761'	System	11 Aug 2020 03:12:10
User entered '10 Aug 2020 22:12'	System	11 Aug 2020 03:12:10

**US3272085**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

**US3272085**

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

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 22:16:40



**US3272085**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 5'	System	07 Aug 2020 22:16:40

**US3272085**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:06**

[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 (a5a7983321c3e006)', Time: '2020-08-11T21:10:06', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '77c0acb7-1268-425d-88cb-9c35dc68c294'	System	12 Aug 2020 03:10:30
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 03:10:30

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:51:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:10:10', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '77c0acb7-1268-425d-88cb-9c35dc68c294'	System	12 Aug 2020 03:10:30
User entered 'No (N)'	System	12 Aug 2020 03:10:30

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:10:13', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '77c0acb7-1268-425d-88cb-9c35dc68c294'	System	12 Aug 2020 03:10:30
User entered 'No (N)'	System	12 Aug 2020 03:10:30

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-08-11T21:10:24', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '77c0acb7-1268-425d-88cb-9c35dc68c294'	System	12 Aug 2020 03:10:30
User entered 'None (1)'	System	12 Aug 2020 03:10:30

**US3272085**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:10:28', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '77c0acb7-1268-425d-88cb-9c35dc68c294'	System	12 Aug 2020 03:10:30
User entered '11 Aug 2020 21:10'	System	12 Aug 2020 03:10:30

**US3272085**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

**US3272085**

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

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 22:16:40



**US3272085**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 6'	System	07 Aug 2020 22:16:40

**US3272085**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

[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 (a5a7983321c3e006)', Time: '2020-08-12T22:28:56', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'e75f55a7-9282-4946-b0ce-e8270f6c00ac'	System	13 Aug 2020 03:29:17
User entered 'None (1)'	System	13 Aug 2020 03:29:17

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:51:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-12T22:29:00', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'e75f55a7-9282-4946-b0ce-e8270f6c00ac'	System	13 Aug 2020 03:29:17
User entered 'No (N)'	System	13 Aug 2020 03:29:17

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:51:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-12T22:29:04', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'e75f55a7-9282-4946-b0ce-e8270f6c00ac'	System	13 Aug 2020 03:29:17
User entered 'No (N)'	System	13 Aug 2020 03:29:17

**US3272085**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

[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 (a5a7983321c3e006)', Time: '2020-08-12T22:29:09', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'e75f55a7-9282-4946-b0ce-e8270f6c00ac'	System	13 Aug 2020 03:29:17
User entered 'None (1)'	System	13 Aug 2020 03:29:17

**US3272085**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-12T22:29:14', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'e75f55a7-9282-4946-b0ce-e8270f6c00ac'	System	13 Aug 2020 03:29:17
User entered '12 Aug 2020 22:29'	System	13 Aug 2020 03:29:17

**US3272085**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

**US3272085**

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

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 22:16:40



**US3272085**

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

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 7'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-08-13T21:02:15', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '41f15775-0bdc-44d2-b3b1-77bc0f28c416'	System	14 Aug 2020 02:02:37
User entered 'None (1)'	System	14 Aug 2020 02:02:37

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:51:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:02:20', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '41f15775-0bdc-44d2-b3b1-77bc0f28c416'	System	14 Aug 2020 02:02:37
User entered 'No (N)'	System	14 Aug 2020 02:02:37

**US3272085**

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

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:02:22', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '41f15775-0bdc-44d2-b3b1-77bc0f28c416'	System	14 Aug 2020 02:02:37
User entered 'No (N)'	System	14 Aug 2020 02:02:37

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-08-13T21:02:30', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '41f15775-0bdc-44d2-b3b1-77bc0f28c416'	System	14 Aug 2020 02:02:37
User entered 'None (1)'	System	14 Aug 2020 02:02:37

**US3272085**

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

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:02:33', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '41f15775-0bdc-44d2-b3b1-77bc0f28c416'	System	14 Aug 2020 02:02:37
User entered '13 Aug 2020 21:02'	System	14 Aug 2020 02:02:37

**US3272085**

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

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

**US3272085**

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

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 22:16:40



**US3272085**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 22:16:40

**US3272085**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:35:10', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2f3341ab-025a-4e6f-8afe-8ae9e65d4b37'	System	07 Aug 2020 22:36:01
User entered 'None (0)'	System	07 Aug 2020 22:36:01

**US3272085**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:35:16', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2f3341ab-025a-4e6f-8afe-8ae9e65d4b37'	System	07 Aug 2020 22:36:01
User entered 'None (0)'	System	07 Aug 2020 22:36:01

**US3272085**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:35:21', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2f3341ab-025a-4e6f-8afe-8ae9e65d4b37'	System	07 Aug 2020 22:36:01
User entered 'None (0)'	System	07 Aug 2020 22:36:01

**US3272085**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:35:32', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2f3341ab-025a-4e6f-8afe-8ae9e65d4b37'	System	07 Aug 2020 22:36:01
User entered 'None (0)'	System	07 Aug 2020 22:36:01

**US3272085**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:35:39', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2f3341ab-025a-4e6f-8afe-8ae9e65d4b37'	System	07 Aug 2020 22:36:01
User entered 'None (0)'	System	07 Aug 2020 22:36:01

**US3272085**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:35:43', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2f3341ab-025a-4e6f-8afe-8ae9e65d4b37'	System	07 Aug 2020 22:36:01
User entered 'None (0)'	System	07 Aug 2020 22:36:01

US3272085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-08-07T17:35:52', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2f3341ab-025a-4e6f-8afe-8ae9e65d4b37'	System	07 Aug 2020 22:36:01
User entered 'No (N)'	System	07 Aug 2020 22:36:01



**US3272085**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:35:56', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2f3341ab-025a-4e6f-8afe-8ae9e65d4b37'	System	07 Aug 2020 22:36:01
User entered '07 Aug 2020 17:35'	System	07 Aug 2020 22:36:01

**US3272085**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 17:11'	System	07 Aug 2020 22:16:40

**US3272085**

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

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 19:41'	System	07 Aug 2020 22:16:40

**US3272085**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 22:16:40

**US3272085**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:09:32', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '61625c11-9245-4f2b-8e9b-bc922e41e6e5'	System	08 Aug 2020 04:10:03
User entered 'None (0)'	System	08 Aug 2020 04:10:03

**US3272085**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:09:38', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '61625c11-9245-4f2b-8e9b-bc922e41e6e5'	System	08 Aug 2020 04:10:03
User entered 'None (0)'	System	08 Aug 2020 04:10:03

**US3272085**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:09:41', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '61625c11-9245-4f2b-8e9b-bc922e41e6e5'	System	08 Aug 2020 04:10:03
User entered 'None (0)'	System	08 Aug 2020 04:10:03

**US3272085**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:09:44', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '61625c11-9245-4f2b-8e9b-bc922e41e6e5'	System	08 Aug 2020 04:10:03
User entered 'None (0)'	System	08 Aug 2020 04:10:03



**US3272085**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:09:46', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '61625c11-9245-4f2b-8e9b-bc922e41e6e5'	System	08 Aug 2020 04:10:03
User entered 'None (0)'	System	08 Aug 2020 04:10:03

**US3272085**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:09:50', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '61625c11-9245-4f2b-8e9b-bc922e41e6e5'	System	08 Aug 2020 04:10:03
User entered 'None (0)'	System	08 Aug 2020 04:10:03

US3272085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-08-07T23:09:54', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '61625c11-9245-4f2b-8e9b-bc922e41e6e5'	System	08 Aug 2020 04:10:03
User entered 'No (N)'	System	08 Aug 2020 04:10:03

**US3272085**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:09:57', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '61625c11-9245-4f2b-8e9b-bc922e41e6e5'	System	08 Aug 2020 04:10:03
User entered '07 Aug 2020 23:09'	System	08 Aug 2020 04:10:03

**US3272085**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 20:36'	System	07 Aug 2020 22:16:40

**US3272085**

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

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 2'	System	07 Aug 2020 22:16:40

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:59:09', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'edf225da-83bb-4662-81d1-b972f414d3d3'	System	09 Aug 2020 01:59:43
User entered 'None (0)'	System	09 Aug 2020 01:59:43



**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:59:15', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'edf225da-83bb-4662-81d1-b972f414d3d3'	System	09 Aug 2020 01:59:43
User entered 'No interference with activity (1)'	System	09 Aug 2020 01:59:43

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:59:24', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'edf225da-83bb-4662-81d1-b972f414d3d3'	System	09 Aug 2020 01:59:43
User entered 'None (0)'	System	09 Aug 2020 01:59:43

US3272085

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:51:06

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:59:27', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'edf225da-83bb-4662-81d1-b972f414d3d3'	System	09 Aug 2020 01:59:43
User entered 'No interference with activity (1)'	System	09 Aug 2020 01:59:43

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:59:29', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'edf225da-83bb-4662-81d1-b972f414d3d3'	System	09 Aug 2020 01:59:43
User entered 'None (0)'	System	09 Aug 2020 01:59:43

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:59:32', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'edf225da-83bb-4662-81d1-b972f414d3d3'	System	09 Aug 2020 01:59:43
User entered 'None (0)'	System	09 Aug 2020 01:59:43

US3272085

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-08-08T20:59:36', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'edf225da-83bb-4662-81d1-b972f414d3d3'	System	09 Aug 2020 01:59:43
User entered 'No (N)'	System	09 Aug 2020 01:59:43

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:59:38', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'edf225da-83bb-4662-81d1-b972f414d3d3'	System	09 Aug 2020 01:59:43
User entered '08 Aug 2020 20:59'	System	09 Aug 2020 01:59:43

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 22:16:40



**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 3'	System	07 Aug 2020 22:16:40

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:31:45', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4234b044-e717-49f3-914b-45e9a0fee3b7'	System	09 Aug 2020 22:32:07
User entered 'None (0)'	System	09 Aug 2020 22:32:07

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:31:48', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4234b044-e717-49f3-914b-45e9a0fee3b7'	System	09 Aug 2020 22:32:07
User entered 'None (0)'	System	09 Aug 2020 22:32:07

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:31:50', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4234b044-e717-49f3-914b-45e9a0fee3b7'	System	09 Aug 2020 22:32:07
User entered 'None (0)'	System	09 Aug 2020 22:32:07

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:31:52', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4234b044-e717-49f3-914b-45e9a0fee3b7'	System	09 Aug 2020 22:32:07
User entered 'None (0)'	System	09 Aug 2020 22:32:07

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:31:55', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4234b044-e717-49f3-914b-45e9a0fee3b7'	System	09 Aug 2020 22:32:07
User entered 'None (0)'	System	09 Aug 2020 22:32:07

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:31:58', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4234b044-e717-49f3-914b-45e9a0fee3b7'	System	09 Aug 2020 22:32:07
User entered 'None (0)'	System	09 Aug 2020 22:32:07



US3272085

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-08-09T17:32:02', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4234b044-e717-49f3-914b-45e9a0fee3b7'	System	09 Aug 2020 22:32:07
User entered 'No (N)'	System	09 Aug 2020 22:32:07

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:32:04', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4234b044-e717-49f3-914b-45e9a0fee3b7'	System	09 Aug 2020 22:32:07
User entered '09 Aug 2020 17:32'	System	09 Aug 2020 22:32:07

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 4'	System	07 Aug 2020 22:16:40

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:12:15', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '68238193-de7e-4640-b0df-7ea7837700bf'	System	11 Aug 2020 03:12:54
User entered 'None (0)'	System	11 Aug 2020 03:12:54

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:12:19', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '68238193-de7e-4640-b0df-7ea7837700bf'	System	11 Aug 2020 03:12:54
User entered 'None (0)'	System	11 Aug 2020 03:12:54

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:12:23', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '68238193-de7e-4640-b0df-7ea7837700bf'	System	11 Aug 2020 03:12:54
User entered 'None (0)'	System	11 Aug 2020 03:12:54



**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:12:33', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '68238193-de7e-4640-b0df-7ea7837700bf'	System	11 Aug 2020 03:12:54
User entered 'None (0)'	System	11 Aug 2020 03:12:54

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:12:35', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '68238193-de7e-4640-b0df-7ea7837700bf'	System	11 Aug 2020 03:12:54
User entered 'None (0)'	System	11 Aug 2020 03:12:54

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:12:38', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '68238193-de7e-4640-b0df-7ea7837700bf'	System	11 Aug 2020 03:12:54
User entered 'None (0)'	System	11 Aug 2020 03:12:54

US3272085

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-08-10T22:12:47', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '68238193-de7e-4640-b0df-7ea7837700bf'	System	11 Aug 2020 03:12:54
User entered 'No (N)'	System	11 Aug 2020 03:12:54

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:12:50', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '68238193-de7e-4640-b0df-7ea7837700bf'	System	11 Aug 2020 03:12:54
User entered '10 Aug 2020 22:12'	System	11 Aug 2020 03:12:54

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 5'	System	07 Aug 2020 22:16:40



**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:10:33', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '5bca7af8-6427-478c-9c16-80b60d0ad9e0'	System	12 Aug 2020 03:11:13
User entered 'None (0)'	System	12 Aug 2020 03:11:13

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:10:37', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '5bca7af8-6427-478c-9c16-80b60d0ad9e0'	System	12 Aug 2020 03:11:13
User entered 'None (0)'	System	12 Aug 2020 03:11:13

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:10:42', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '5bca7af8-6427-478c-9c16-80b60d0ad9e0'	System	12 Aug 2020 03:11:13
User entered 'None (0)'	System	12 Aug 2020 03:11:13

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:10:47', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '5bca7af8-6427-478c-9c16-80b60d0ad9e0'	System	12 Aug 2020 03:11:13
User entered 'No interference with activity (1)'	System	12 Aug 2020 03:11:13

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:10:56', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '5bca7af8-6427-478c-9c16-80b60d0ad9e0'	System	12 Aug 2020 03:11:13
User entered 'None (0)'	System	12 Aug 2020 03:11:13

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:10:59', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '5bca7af8-6427-478c-9c16-80b60d0ad9e0'	System	12 Aug 2020 03:11:13
User entered 'None (0)'	System	12 Aug 2020 03:11:13

US3272085

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-08-11T21:11:07', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '5bca7af8-6427-478c-9c16-80b60d0ad9e0'	System	12 Aug 2020 03:11:13
User entered 'No (N)'	System	12 Aug 2020 03:11:13

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:11:09', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '5bca7af8-6427-478c-9c16-80b60d0ad9e0'	System	12 Aug 2020 03:11:13
User entered '11 Aug 2020 21:11'	System	12 Aug 2020 03:11:13



**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

**US3272085**

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

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

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

**US3272085**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 6'	System	07 Aug 2020 22:16:40

**US3272085**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-12T22:29:26', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'febcd561-25fa-4e06-9430-25656c1af062'	System	13 Aug 2020 03:29:57
User entered 'None (0)'	System	13 Aug 2020 03:29:57

**US3272085**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-12T22:29:33', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'febcd561-25fa-4e06-9430-25656c1af062'	System	13 Aug 2020 03:29:57
User entered 'No interference with activity (1)'	System	13 Aug 2020 03:29:57

**US3272085**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-12T22:29:37', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'febcd561-25fa-4e06-9430-25656c1af062'	System	13 Aug 2020 03:29:57
User entered 'No interference with activity (1)'	System	13 Aug 2020 03:29:57

**US3272085**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-12T22:29:40', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'febcd561-25fa-4e06-9430-25656c1af062'	System	13 Aug 2020 03:29:57
User entered 'No interference with activity (1)'	System	13 Aug 2020 03:29:57

**US3272085**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-12T22:29:44', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'febcd561-25fa-4e06-9430-25656c1af062'	System	13 Aug 2020 03:29:57
User entered 'None (0)'	System	13 Aug 2020 03:29:57



**US3272085**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-12T22:29:47', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'febcd561-25fa-4e06-9430-25656c1af062'	System	13 Aug 2020 03:29:57
User entered 'None (0)'	System	13 Aug 2020 03:29:57

US3272085

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-08-12T22:29:50', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'febcd561-25fa-4e06-9430-25656c1af062'	System	13 Aug 2020 03:29:57
User entered 'No (N)'	System	13 Aug 2020 03:29:57

**US3272085**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-12T22:29:55', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'febcd561-25fa-4e06-9430-25656c1af062'	System	13 Aug 2020 03:29:57
User entered '12 Aug 2020 22:29'	System	13 Aug 2020 03:29:57

**US3272085**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

**US3272085**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

**US3272085**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 7'	System	07 Aug 2020 22:16:40

**US3272085**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:02:37', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7fceb181-76a0-44e5-a2b5-3acc2679b19f'	System	14 Aug 2020 02:03:06
User entered 'None (0)'	System	14 Aug 2020 02:03:06

**US3272085**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:02:40', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7fceb181-76a0-44e5-a2b5-3acc2679b19f'	System	14 Aug 2020 02:03:06
User entered 'None (0)'	System	14 Aug 2020 02:03:06



**US3272085**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:02:47', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7fceb181-76a0-44e5-a2b5-3acc2679b19f'	System	14 Aug 2020 02:03:06
User entered 'None (0)'	System	14 Aug 2020 02:03:06

US3272085

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:51:06

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:02:50', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7fceb181-76a0-44e5-a2b5-3acc2679b19f'	System	14 Aug 2020 02:03:06
User entered 'None (0)'	System	14 Aug 2020 02:03:06

**US3272085**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:02:53', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7fceb181-76a0-44e5-a2b5-3acc2679b19f'	System	14 Aug 2020 02:03:06
User entered 'None (0)'	System	14 Aug 2020 02:03:06

**US3272085**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:02:56', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7fceb181-76a0-44e5-a2b5-3acc2679b19f'	System	14 Aug 2020 02:03:06
User entered 'None (0)'	System	14 Aug 2020 02:03:06

US3272085

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-08-13T21:02:59', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7fceb181-76a0-44e5-a2b5-3acc2679b19f'	System	14 Aug 2020 02:03:06
User entered 'No (N)'	System	14 Aug 2020 02:03:06

**US3272085**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:03:01', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7fceb181-76a0-44e5-a2b5-3acc2679b19f'	System	14 Aug 2020 02:03:06
User entered '13 Aug 2020 21:03'	System	14 Aug 2020 02:03:06

**US3272085**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

**US3272085**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 22:16:40



**US3272085**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 03:29:57
User entered 'Day 8'	System	13 Aug 2020 03:29:57

US3272085

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-08-15T00:02:10', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'e033c075-60cf-4c5d-a26a-a46a9e31cbc8'	System	15 Aug 2020 05:02:22
User entered 'No (N)'	System	15 Aug 2020 05:02:22

**US3272085**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-15T00:02:18', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'e033c075-60cf-4c5d-a26a-a46a9e31cbc8'	System	15 Aug 2020 05:02:22
User entered '15 Aug 2020 00:02'	System	15 Aug 2020 05:02:22

**US3272085**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 03:29:57

**US3272085**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 03:29:57

US3272085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:45:59

US3272085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 21:45:59

US3272085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Aug 2020 21:45:59



**US3272085**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:06**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 21:45:59

US3272085

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:46:06

**US3272085**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:06**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Aug 2020 21:46:06

US3272085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:46:18

US3272085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 21:46:18

**US3272085**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:06**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Aug 2020 21:46:18

**US3272085**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:06**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 21:46:18

US3272085

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:46:22



**US3272085**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:06**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Aug 2020 21:46:22

US3272085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 21:44:33

US3272085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 21:44:33

US3272085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

[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 21:44:33

**US3272085**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:06**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 21:44:33

US3272085

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 21:44:41

**US3272085**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:06**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Sep 2020 21:44:41

US3272085

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:15:46



US3272085

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '04 Sep 2020'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:15:46

US3272085

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:15:46

**US3272085**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:06**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	05 Sep 2020 02:15:46

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Sep 2020'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:17:18

**US3272085**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:06**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User entered '14:15' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 23:06:02
User entered '14:10'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:17:18

**US3272085**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 14:15'	System	13 Nov 2020 23:06:02
User entered '04 Sep 2020 14:10'	System	05 Sep 2020 02:17:18



US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.7' C	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

Pulse (xxx)

Audit	User	Time (GMT)
User entered '73'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:17:18

**US3272085**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '123'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:17:18



**US3272085**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '82'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:51:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '4 Sep 2020'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User entered '15:40'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:17:18

**US3272085**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '4 Sep 2020 15:40'	System	05 Sep 2020 02:17:18



US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.7' C	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '67'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:17:18

**US3272085**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '12'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '123'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:17:18



**US3272085**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '85'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:51:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:06

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:17:28

US3272085

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:06

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '4 Sep 2020'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:17:28

US3272085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	04 Sep 2020 20:17:34

US3272085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	04 Sep 2020 20:17:34

US3272085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

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)	04 Sep 2020 20:17:34



**US3272085**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:51:06**

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 20:17:34

US3272085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '04 Sep 2020'	Kayla Flege (b) (4) (b) (4)	04 Sep 2020 20:17:34

US3272085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '15:09'	Kayla Flege (b) (4) (b) (4)	04 Sep 2020 20:17:34

**US3272085**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:51:06**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 15:09'	System	04 Sep 2020 20:17:34

US3272085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Kayla Flege (b) (4) (b) (4)	04 Sep 2020 20:17:34

US3272085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	04 Sep 2020 20:17:34

US3272085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:51:06

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 20:17:34

US3272085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:17:50



US3272085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '4 Sep 2020'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:17:50

US3272085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:06

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '14:31'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:17:50

**US3272085**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:51:06**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '4 Sep 2020 14:31'	System	05 Sep 2020 02:17:50

US3272085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:51:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Sep 2020'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:18:09

US3272085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:51:06

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:18:09

US3272085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:51:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:18:09

US3272085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:51:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '14:24'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:18:09

**US3272085**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 14:24'	System	05 Sep 2020 02:18:09



US3272085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:51:06

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:18:09

US3272085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:51:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:18:09

US3272085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:51:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:18:09

**US3272085**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Sep 2020 02:18:09

US3272085

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:18:14

**US3272085**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:06**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 02:18:14

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:43:07', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'ec5359da-cee8-43a3-8167-bf06e59cc8a8'	System	04 Sep 2020 20:43:22
User entered 'Yes (Y)'	System	04 Sep 2020 20:43:22



US3272085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:43:12', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'ec5359da-cee8-43a3-8167-bf06e59cc8a8'	System	04 Sep 2020 20:43:22
User entered '98.2'	System	04 Sep 2020 20:43:22

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:43:16', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'ec5359da-cee8-43a3-8167-bf06e59cc8a8'	System	04 Sep 2020 20:43:22
User entered 'No (N)'	System	04 Sep 2020 20:43:22

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:43:19', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'ec5359da-cee8-43a3-8167-bf06e59cc8a8'	System	04 Sep 2020 20:43:22
User entered '04 Sep 2020 15:43'	System	04 Sep 2020 20:43:22

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 15:29'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 17:59'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:30:03', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'a6a8f30f-317a-48e7-903d-26dde246f543'	System	05 Sep 2020 07:30:24
User entered 'Yes (Y)'	System	05 Sep 2020 07:30:24

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:30:11', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'a6a8f30f-317a-48e7-903d-26dde246f543'	System	05 Sep 2020 07:30:24
User entered '97.9'	System	05 Sep 2020 07:30:24



US3272085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:30:15', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'a6a8f30f-317a-48e7-903d-26dde246f543'	System	05 Sep 2020 07:30:24
User entered 'No (N)'	System	05 Sep 2020 07:30:24

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:30:19', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'a6a8f30f-317a-48e7-903d-26dde246f543'	System	05 Sep 2020 07:30:24
User entered '05 Sep 2020 02:30'	System	05 Sep 2020 07:30:24

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 18:54'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 2'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:06**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:19:12', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fec4da26-6556-428e-bb9e-ee5d6776dfdb'	System	06 Sep 2020 02:19:27
User entered 'Yes (Y)'	System	06 Sep 2020 02:19:27

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:51:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:19:17', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fec4da26-6556-428e-bb9e-ee5d6776dfdb'	System	06 Sep 2020 02:19:27
User entered '97.9'	System	06 Sep 2020 02:19:27

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:51:06

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:19:20', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fec4da26-6556-428e-bb9e-ee5d6776dfdb'	System	06 Sep 2020 02:19:27
User entered 'No (N)'	System	06 Sep 2020 02:19:27



**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:19:23', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fec4da26-6556-428e-bb9e-ee5d6776dfdb'	System	06 Sep 2020 02:19:27
User entered '05 Sep 2020 21:19'	System	06 Sep 2020 02:19:27

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 3'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:51:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:53:43', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'e5908ffc-11a4-498e-a039-bb38caeb8a7a'	System	07 Sep 2020 02:53:57
User entered 'Yes (Y)'	System	07 Sep 2020 02:53:57

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:51:06**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:53:48', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'e5908ffc-11a4-498e-a039-bb38caeb8a7a'	System	07 Sep 2020 02:53:57
User entered '98.1'	System	07 Sep 2020 02:53:57

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:51:06

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:53:51', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'e5908ffc-11a4-498e-a039-bb38caeb8a7a'	System	07 Sep 2020 02:53:57
User entered 'No (N)'	System	07 Sep 2020 02:53:57

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:53:53', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'e5908ffc-11a4-498e-a039-bb38caeb8a7a'	System	07 Sep 2020 02:53:57
User entered '06 Sep 2020 21:53'	System	07 Sep 2020 02:53:57



**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 4'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:06**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:39:02', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'bce719f7-831b-4908-872e-d9472e964c38'	System	08 Sep 2020 05:39:17
User entered 'Yes (Y)'	System	08 Sep 2020 05:39:17

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:51:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:39:08', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'bce719f7-831b-4908-872e-d9472e964c38'	System	08 Sep 2020 05:39:17
User entered '98.1'	System	08 Sep 2020 05:39:17

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:51:06

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:39:11', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'bce719f7-831b-4908-872e-d9472e964c38'	System	08 Sep 2020 05:39:17
User entered 'No (N)'	System	08 Sep 2020 05:39:17

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:39:15', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'bce719f7-831b-4908-872e-d9472e964c38'	System	08 Sep 2020 05:39:17
User entered '08 Sep 2020 00:39'	System	08 Sep 2020 05:39:17

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:51:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 20:17:34



**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 5'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:51:06**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:27:25', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '373b149c-5c6e-4daf-8873-19d5392d58de'	System	09 Sep 2020 01:27:37
User entered 'Yes (Y)'	System	09 Sep 2020 01:27:37

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:51:06**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:27:29', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '373b149c-5c6e-4daf-8873-19d5392d58de'	System	09 Sep 2020 01:27:37
User entered '98.2'	System	09 Sep 2020 01:27:37

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:51:06

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:27:32', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '373b149c-5c6e-4daf-8873-19d5392d58de'	System	09 Sep 2020 01:27:37
User entered 'No (N)'	System	09 Sep 2020 01:27:37

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:27:34', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '373b149c-5c6e-4daf-8873-19d5392d58de'	System	09 Sep 2020 01:27:37
User entered '08 Sep 2020 20:27'	System	09 Sep 2020 01:27:37

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 20:17:34



**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 6'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:00:25', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4f06efa2-0fea-424d-b549-10e24f381f30'	System	10 Sep 2020 05:00:37
User entered 'Yes (Y)'	System	10 Sep 2020 05:00:37

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:51:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:00:30', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4f06efa2-0fea-424d-b549-10e24f381f30'	System	10 Sep 2020 05:00:37
User entered '97.9'	System	10 Sep 2020 05:00:37

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:51:06

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:00:32', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4f06efa2-0fea-424d-b549-10e24f381f30'	System	10 Sep 2020 05:00:37
User entered 'No (N)'	System	10 Sep 2020 05:00:37

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:00:35', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4f06efa2-0fea-424d-b549-10e24f381f30'	System	10 Sep 2020 05:00:37
User entered '10 Sep 2020 00:00'	System	10 Sep 2020 05:00:37

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 7'	System	04 Sep 2020 20:17:34



**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:01', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '1638072f-eb4b-4307-93a7-a1aca4dade68'	System	10 Sep 2020 23:35:12
User entered 'Yes (Y)'	System	10 Sep 2020 23:35:12

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:05', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '1638072f-eb4b-4307-93a7-a1aca4dade68'	System	10 Sep 2020 23:35:12
User entered '98.2'	System	10 Sep 2020 23:35:12

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:51:06

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:08', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '1638072f-eb4b-4307-93a7-a1aca4dade68'	System	10 Sep 2020 23:35:12
User entered 'No (N)'	System	10 Sep 2020 23:35:12

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:10', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '1638072f-eb4b-4307-93a7-a1aca4dade68'	System	10 Sep 2020 23:35:12
User entered '10 Sep 2020 18:35'	System	10 Sep 2020 23:35:12

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

[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 (a5a7983321c3e006)', Time: '2020-09-04T15:43:40', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '324fba70-2194-463c-a46a-fb418b846a47'	System	04 Sep 2020 20:44:03
User entered 'None (1)'	System	04 Sep 2020 20:44:03



US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:43:48', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '324fba70-2194-463c-a46a-fb418b846a47'	System	04 Sep 2020 20:44:03
User entered 'No (N)'	System	04 Sep 2020 20:44:03

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:43:53', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '324fba70-2194-463c-a46a-fb418b846a47'	System	04 Sep 2020 20:44:03
User entered 'No (N)'	System	04 Sep 2020 20:44:03

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-09-04T15:43:56', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '324fba70-2194-463c-a46a-fb418b846a47'	System	04 Sep 2020 20:44:03
User entered 'None (1)'	System	04 Sep 2020 20:44:03

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:43:59', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '324fba70-2194-463c-a46a-fb418b846a47'	System	04 Sep 2020 20:44:03
User entered '04 Sep 2020 15:43'	System	04 Sep 2020 20:44:03

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 15:29'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 17:59'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-09-05T02:30:26', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'aeaa8c59-9246-4f44-adff-9edab7e9d9c9'	System	05 Sep 2020 07:30:55
User entered 'None (1)'	System	05 Sep 2020 07:30:55



US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:30:31', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'aeaa8c59-9246-4f44-adff-9edab7e9d9c9'	System	05 Sep 2020 07:30:55
User entered 'No (N)'	System	05 Sep 2020 07:30:55

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:30:37', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'aeaa8c59-9246-4f44-adff-9edab7e9d9c9'	System	05 Sep 2020 07:30:55
User entered 'No (N)'	System	05 Sep 2020 07:30:55

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-09-05T02:30:47', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'aeaa8c59-9246-4f44-adff-9edab7e9d9c9'	System	05 Sep 2020 07:30:55
User entered 'None (1)'	System	05 Sep 2020 07:30:55

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:30:50', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'aeaa8c59-9246-4f44-adff-9edab7e9d9c9'	System	05 Sep 2020 07:30:55
User entered '05 Sep 2020 02:30'	System	05 Sep 2020 07:30:55

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 18:54'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 2'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:06**

[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 (a5a7983321c3e006)', Time: '2020-09-05T21:19:30', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '8aedic738-6c2e-40dc-a05c-243c24991edb'	System	06 Sep 2020 02:20:04
User entered 'None (1)'	System	06 Sep 2020 02:20:04



US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:51:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:19:42', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '8aedc738-6c2e-40dc-a05c-243c24991edb'	System	06 Sep 2020 02:20:04
User entered 'No (N)'	System	06 Sep 2020 02:20:04

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:51:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:19:45', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '8aedc738-6c2e-40dc-a05c-243c24991edb'	System	06 Sep 2020 02:20:04
User entered 'No (N)'	System	06 Sep 2020 02:20:04

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-09-05T21:19:51', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '8aedc738-6c2e-40dc-a05c-243c24991edb'	System	06 Sep 2020 02:20:04
User entered 'None (1)'	System	06 Sep 2020 02:20:04

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:19:59', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '8aedc738-6c2e-40dc-a05c-243c24991edb'	System	06 Sep 2020 02:20:04
User entered '05 Sep 2020 21:19'	System	06 Sep 2020 02:20:04

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 3'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:06**

[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 (a5a7983321c3e006)', Time: '2020-09-06T21:53:57', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2275bbcf-824d-4ec7-b4f5-5232c2f6e66f'	System	07 Sep 2020 02:54:10
User entered 'None (1)'	System	07 Sep 2020 02:54:10



US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:51:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:53:59', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2275bbcf-824d-4ec7-b4f5-5232c2f6e66f'	System	07 Sep 2020 02:54:10
User entered 'No (N)'	System	07 Sep 2020 02:54:10

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:51:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:54:02', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2275bbcf-824d-4ec7-b4f5-5232c2f6e66f'	System	07 Sep 2020 02:54:10
User entered 'No (N)'	System	07 Sep 2020 02:54:10

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:06**

[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 (a5a7983321c3e006)', Time: '2020-09-06T21:54:04', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2275bbcf-824d-4ec7-b4f5-5232c2f6e66f'	System	07 Sep 2020 02:54:10
User entered 'None (1)'	System	07 Sep 2020 02:54:10

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:54:06', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2275bbcf-824d-4ec7-b4f5-5232c2f6e66f'	System	07 Sep 2020 02:54:10
User entered '06 Sep 2020 21:54'	System	07 Sep 2020 02:54:10

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 4'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:06**

[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 (a5a7983321c3e006)', Time: '2020-09-08T00:39:29', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'edeb7092-cf96-4659-b6a6-3284bbcf5560'	System	08 Sep 2020 05:39:48
User entered 'None (1)'	System	08 Sep 2020 05:39:48



US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:51:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:39:33', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'edeb7092-cf96-4659-b6a6-3284bbcf5560'	System	08 Sep 2020 05:39:48
User entered 'No (N)'	System	08 Sep 2020 05:39:48

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:51:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:39:37', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'edeb7092-cf96-4659-b6a6-3284bbcf5560'	System	08 Sep 2020 05:39:48
User entered 'No (N)'	System	08 Sep 2020 05:39:48

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-09-08T00:39:42', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'edeb7092-cf96-4659-b6a6-3284bbcf5560'	System	08 Sep 2020 05:39:48
User entered 'None (1)'	System	08 Sep 2020 05:39:48

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:39:45', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'edeb7092-cf96-4659-b6a6-3284bbcf5560'	System	08 Sep 2020 05:39:48
User entered '08 Sep 2020 00:39'	System	08 Sep 2020 05:39:48

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 5'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-09-08T20:27:39', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'd2b19296-4885-497f-b49b-0483bd53293d'	System	09 Sep 2020 01:28:03
User entered 'None (1)'	System	09 Sep 2020 01:28:03



US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:51:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:27:42', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'd2b19296-4885-497f-b49b-0483bd53293d'	System	09 Sep 2020 01:28:03
User entered 'No (N)'	System	09 Sep 2020 01:28:03

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:51:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:27:45', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'd2b19296-4885-497f-b49b-0483bd53293d'	System	09 Sep 2020 01:28:03
User entered 'No (N)'	System	09 Sep 2020 01:28:03

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:06**

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 (a5a7983321c3e006)', Time: '2020-09-08T20:27:57', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'd2b19296-4885-497f-b49b-0483bd53293d'	System	09 Sep 2020 01:28:03
User entered 'None (1)'	System	09 Sep 2020 01:28:03

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:27:59', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'd2b19296-4885-497f-b49b-0483bd53293d'	System	09 Sep 2020 01:28:03
User entered '08 Sep 2020 20:27'	System	09 Sep 2020 01:28:03

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 6'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-09-10T00:00:39', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'd892a9e9-9dee-491e-9648-b981c2ce6554'	System	10 Sep 2020 05:00:56
User entered 'None (1)'	System	10 Sep 2020 05:00:56



US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:51:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:00:41', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'd892a9e9-9dee-491e-9648-b981c2ce6554'	System	10 Sep 2020 05:00:56
User entered 'No (N)'	System	10 Sep 2020 05:00:56

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:51:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:00:44', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'd892a9e9-9dee-491e-9648-b981c2ce6554'	System	10 Sep 2020 05:00:56
User entered 'No (N)'	System	10 Sep 2020 05:00:56

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-09-10T00:00:49', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'd892a9e9-9dee-491e-9648-b981c2ce6554'	System	10 Sep 2020 05:00:56
User entered 'None (1)'	System	10 Sep 2020 05:00:56

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:00:51', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'd892a9e9-9dee-491e-9648-b981c2ce6554'	System	10 Sep 2020 05:00:56
User entered '10 Sep 2020 00:00'	System	10 Sep 2020 05:00:56

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 7'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

[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 (a5a7983321c3e006)', Time: '2020-09-10T18:35:15', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'ba24bc20-7089-4533-9a0e-f377514da00c'	System	10 Sep 2020 23:35:36
User entered 'None (1)'	System	10 Sep 2020 23:35:36



US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:51:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:24', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'ba24bc20-7089-4533-9a0e-f377514da00c'	System	10 Sep 2020 23:35:36
User entered 'No (N)'	System	10 Sep 2020 23:35:36

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:51:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:27', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'ba24bc20-7089-4533-9a0e-f377514da00c'	System	10 Sep 2020 23:35:36
User entered 'No (N)'	System	10 Sep 2020 23:35:36

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

[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 (a5a7983321c3e006)', Time: '2020-09-10T18:35:31', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'ba24bc20-7089-4533-9a0e-f377514da00c'	System	10 Sep 2020 23:35:36
User entered 'None (1)'	System	10 Sep 2020 23:35:36

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:34', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'ba24bc20-7089-4533-9a0e-f377514da00c'	System	10 Sep 2020 23:35:36
User entered '10 Sep 2020 18:35'	System	10 Sep 2020 23:35:36

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:44:25', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fd80ac08-c6a6-467e-be2c-484e4bbe2a5b'	System	04 Sep 2020 20:44:45
User entered 'None (0)'	System	04 Sep 2020 20:44:45



**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:44:30', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fd80ac08-c6a6-467e-be2c-484e4bbe2a5b'	System	04 Sep 2020 20:44:45
User entered 'None (0)'	System	04 Sep 2020 20:44:45

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:44:32', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fd80ac08-c6a6-467e-be2c-484e4bbe2a5b'	System	04 Sep 2020 20:44:45
User entered 'None (0)'	System	04 Sep 2020 20:44:45

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:44:34', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fd80ac08-c6a6-467e-be2c-484e4bbe2a5b'	System	04 Sep 2020 20:44:45
User entered 'None (0)'	System	04 Sep 2020 20:44:45

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:44:35', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fd80ac08-c6a6-467e-be2c-484e4bbe2a5b'	System	04 Sep 2020 20:44:45
User entered 'None (0)'	System	04 Sep 2020 20:44:45

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:44:37', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fd80ac08-c6a6-467e-be2c-484e4bbe2a5b'	System	04 Sep 2020 20:44:45
User entered 'None (0)'	System	04 Sep 2020 20:44:45

US3272085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-09-04T15:44:40', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fd80ac08-c6a6-467e-be2c-484e4bbe2a5b'	System	04 Sep 2020 20:44:45
User entered 'No (N)'	System	04 Sep 2020 20:44:45

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:44:43', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fd80ac08-c6a6-467e-be2c-484e4bbe2a5b'	System	04 Sep 2020 20:44:45
User entered '04 Sep 2020 15:44'	System	04 Sep 2020 20:44:45

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 15:29'	System	04 Sep 2020 20:17:34



**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 17:59'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:30:55', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '728d3626-18ee-401a-9269-0df4531ba656'	System	05 Sep 2020 07:31:26
User entered 'None (0)'	System	05 Sep 2020 07:31:26

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:31:00', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '728d3626-18ee-401a-9269-0df4531ba656'	System	05 Sep 2020 07:31:26
User entered 'None (0)'	System	05 Sep 2020 07:31:26

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:31:04', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '728d3626-18ee-401a-9269-0df4531ba656'	System	05 Sep 2020 07:31:26
User entered 'None (0)'	System	05 Sep 2020 07:31:26

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:31:08', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '728d3626-18ee-401a-9269-0df4531ba656'	System	05 Sep 2020 07:31:26
User entered 'None (0)'	System	05 Sep 2020 07:31:26

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:31:12', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '728d3626-18ee-401a-9269-0df4531ba656'	System	05 Sep 2020 07:31:26
User entered 'None (0)'	System	05 Sep 2020 07:31:26

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:31:15', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '728d3626-18ee-401a-9269-0df4531ba656'	System	05 Sep 2020 07:31:26
User entered 'None (0)'	System	05 Sep 2020 07:31:26



US3272085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-09-05T02:31:19', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '728d3626-18ee-401a-9269-0df4531ba656'	System	05 Sep 2020 07:31:26
User entered 'No (N)'	System	05 Sep 2020 07:31:26

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:31:22', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '728d3626-18ee-401a-9269-0df4531ba656'	System	05 Sep 2020 07:31:26
User entered '05 Sep 2020 02:31'	System	05 Sep 2020 07:31:26

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 18:54'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 2'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:06**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:20:03', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'b62f6102-681e-4f62-8337-817ff7f52641'	System	06 Sep 2020 02:20:27
User entered 'None (0)'	System	06 Sep 2020 02:20:27

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:06**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:20:09', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'b62f6102-681e-4f62-8337-817ff7f52641'	System	06 Sep 2020 02:20:27
User entered 'None (0)'	System	06 Sep 2020 02:20:27

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:06**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:20:12', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'b62f6102-681e-4f62-8337-817ff7f52641'	System	06 Sep 2020 02:20:27
User entered 'None (0)'	System	06 Sep 2020 02:20:27



**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:06**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:20:15', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'b62f6102-681e-4f62-8337-817ff7f52641'	System	06 Sep 2020 02:20:27
User entered 'None (0)'	System	06 Sep 2020 02:20:27

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:06**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:20:17', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'b62f6102-681e-4f62-8337-817ff7f52641'	System	06 Sep 2020 02:20:27
User entered 'None (0)'	System	06 Sep 2020 02:20:27

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:06**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:20:19', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'b62f6102-681e-4f62-8337-817ff7f52641'	System	06 Sep 2020 02:20:27
User entered 'None (0)'	System	06 Sep 2020 02:20:27

US3272085

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-09-05T21:20:21', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'b62f6102-681e-4f62-8337-817ff7f52641'	System	06 Sep 2020 02:20:27
User entered 'No (N)'	System	06 Sep 2020 02:20:27

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:20:24', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'b62f6102-681e-4f62-8337-817ff7f52641'	System	06 Sep 2020 02:20:27
User entered '05 Sep 2020 21:20'	System	06 Sep 2020 02:20:27

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 3'	System	04 Sep 2020 20:17:34



**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:06**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:54:10', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7e144e86-68fe-494c-a27a-0681b1d1f4f8'	System	07 Sep 2020 02:54:25
User entered 'None (0)'	System	07 Sep 2020 02:54:25

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:06**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:54:11', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7e144e86-68fe-494c-a27a-0681b1d1f4f8'	System	07 Sep 2020 02:54:25
User entered 'None (0)'	System	07 Sep 2020 02:54:25

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:06**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:54:13', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7e144e86-68fe-494c-a27a-0681b1d1f4f8'	System	07 Sep 2020 02:54:25
User entered 'None (0)'	System	07 Sep 2020 02:54:25

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:06**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:54:15', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7e144e86-68fe-494c-a27a-0681b1d1f4f8'	System	07 Sep 2020 02:54:25
User entered 'None (0)'	System	07 Sep 2020 02:54:25

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:06**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:54:17', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7e144e86-68fe-494c-a27a-0681b1d1f4f8'	System	07 Sep 2020 02:54:25
User entered 'None (0)'	System	07 Sep 2020 02:54:25

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:06**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:54:19', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7e144e86-68fe-494c-a27a-0681b1d1f4f8'	System	07 Sep 2020 02:54:25
User entered 'None (0)'	System	07 Sep 2020 02:54:25

US3272085

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-09-06T21:54:21', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7e144e86-68fe-494c-a27a-0681b1d1f4f8'	System	07 Sep 2020 02:54:25
User entered 'No (N)'	System	07 Sep 2020 02:54:25

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:54:23', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7e144e86-68fe-494c-a27a-0681b1d1f4f8'	System	07 Sep 2020 02:54:25
User entered '06 Sep 2020 21:54'	System	07 Sep 2020 02:54:25



**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 4'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:06**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:39:50', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'dda71fdd-16b6-48d0-af3f-00ca97ca977c'	System	08 Sep 2020 05:40:29
User entered 'None (0)'	System	08 Sep 2020 05:40:29

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:06**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:39:59', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'dda71fdd-16b6-48d0-af3f-00ca97ca977c'	System	08 Sep 2020 05:40:29
User entered 'None (0)'	System	08 Sep 2020 05:40:29

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:06**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:40:04', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'dda71fdd-16b6-48d0-af3f-00ca97ca977c'	System	08 Sep 2020 05:40:29
User entered 'No interference with activity (1)'	System	08 Sep 2020 05:40:29

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:06**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:40:08', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'dda71fdd-16b6-48d0-af3f-00ca97ca977c'	System	08 Sep 2020 05:40:29
User entered 'No interference with activity (1)'	System	08 Sep 2020 05:40:29

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:06**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:40:12', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'dda71fdd-16b6-48d0-af3f-00ca97ca977c'	System	08 Sep 2020 05:40:29
User entered 'None (0)'	System	08 Sep 2020 05:40:29



**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:06**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:40:16', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'dda71fdd-16b6-48d0-af3f-00ca97ca977c'	System	08 Sep 2020 05:40:29
User entered 'None (0)'	System	08 Sep 2020 05:40:29

US3272085

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-09-08T00:40:23', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'dda71fdd-16b6-48d0-af3f-00ca97ca977c'	System	08 Sep 2020 05:40:29
User entered 'No (N)'	System	08 Sep 2020 05:40:29

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:40:26', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'dda71fdd-16b6-48d0-af3f-00ca97ca977c'	System	08 Sep 2020 05:40:29
User entered '08 Sep 2020 00:40'	System	08 Sep 2020 05:40:29

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 5'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:06**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:28:11', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '108972ac-ecb9-401c-b7d4-d64094ee520e'	System	09 Sep 2020 01:28:38
User entered 'None (0)'	System	09 Sep 2020 01:28:38

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:06**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:28:15', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '108972ac-ecb9-401c-b7d4-d64094ee520e'	System	09 Sep 2020 01:28:38
User entered 'No interference with activity (1)'	System	09 Sep 2020 01:28:38



**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:06**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:28:20', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '108972ac-ecb9-401c-b7d4-d64094ee520e'	System	09 Sep 2020 01:28:38
User entered 'None (0)'	System	09 Sep 2020 01:28:38

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:06**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:28:23', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '108972ac-ecb9-401c-b7d4-d64094ee520e'	System	09 Sep 2020 01:28:38
User entered 'None (0)'	System	09 Sep 2020 01:28:38

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:06**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:28:25', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '108972ac-ecb9-401c-b7d4-d64094ee520e'	System	09 Sep 2020 01:28:38
User entered 'None (0)'	System	09 Sep 2020 01:28:38

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:06**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:28:28', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '108972ac-ecb9-401c-b7d4-d64094ee520e'	System	09 Sep 2020 01:28:38
User entered 'None (0)'	System	09 Sep 2020 01:28:38

US3272085

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-09-08T20:28:30', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '108972ac-ecb9-401c-b7d4-d64094ee520e'	System	09 Sep 2020 01:28:38
User entered 'No (N)'	System	09 Sep 2020 01:28:38

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:28:33', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '108972ac-ecb9-401c-b7d4-d64094ee520e'	System	09 Sep 2020 01:28:38
User entered '08 Sep 2020 20:28'	System	09 Sep 2020 01:28:38

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 20:17:34



**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 6'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:00:55', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '681eafff-7915-4158-9824-400cb23e2eea'	System	10 Sep 2020 05:01:14
User entered 'None (0)'	System	10 Sep 2020 05:01:14

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:00:57', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '681eafff-7915-4158-9824-400cb23e2eea'	System	10 Sep 2020 05:01:14
User entered 'None (0)'	System	10 Sep 2020 05:01:14

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:00:59', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '681eafff-7915-4158-9824-400cb23e2eea'	System	10 Sep 2020 05:01:14
User entered 'None (0)'	System	10 Sep 2020 05:01:14

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:01:01', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '681eafff-7915-4158-9824-400cb23e2eea'	System	10 Sep 2020 05:01:14
User entered 'None (0)'	System	10 Sep 2020 05:01:14

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:01:03', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '681eafff-7915-4158-9824-400cb23e2eea'	System	10 Sep 2020 05:01:14
User entered 'None (0)'	System	10 Sep 2020 05:01:14

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:01:05', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '681eafff-7915-4158-9824-400cb23e2eea'	System	10 Sep 2020 05:01:14
User entered 'None (0)'	System	10 Sep 2020 05:01:14

US3272085

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-09-10T00:01:09', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '681eafff-7915-4158-9824-400cb23e2eea'	System	10 Sep 2020 05:01:14
User entered 'No (N)'	System	10 Sep 2020 05:01:14



**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:01:11', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '681eafff-7915-4158-9824-400cb23e2eea'	System	10 Sep 2020 05:01:14
User entered '10 Sep 2020 00:01'	System	10 Sep 2020 05:01:14

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 7'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:38', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4c9106f9-4d79-4c63-9f1f-2bf178fe6163'	System	10 Sep 2020 23:36:03
User entered 'None (0)'	System	10 Sep 2020 23:36:03

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:40', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4c9106f9-4d79-4c63-9f1f-2bf178fe6163'	System	10 Sep 2020 23:36:03
User entered 'None (0)'	System	10 Sep 2020 23:36:03

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:43', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4c9106f9-4d79-4c63-9f1f-2bf178fe6163'	System	10 Sep 2020 23:36:03
User entered 'None (0)'	System	10 Sep 2020 23:36:03

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:46', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4c9106f9-4d79-4c63-9f1f-2bf178fe6163'	System	10 Sep 2020 23:36:03
User entered 'None (0)'	System	10 Sep 2020 23:36:03



**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:49', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4c9106f9-4d79-4c63-9f1f-2bf178fe6163'	System	10 Sep 2020 23:36:03
User entered 'None (0)'	System	10 Sep 2020 23:36:03

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:51', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4c9106f9-4d79-4c63-9f1f-2bf178fe6163'	System	10 Sep 2020 23:36:03
User entered 'None (0)'	System	10 Sep 2020 23:36:03

US3272085

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:51:06

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 (a5a7983321c3e006)', Time: '2020-09-10T18:35:57', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4c9106f9-4d79-4c63-9f1f-2bf178fe6163'	System	10 Sep 2020 23:36:03
User entered 'No (N)'	System	10 Sep 2020 23:36:03

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:59', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4c9106f9-4d79-4c63-9f1f-2bf178fe6163'	System	10 Sep 2020 23:36:03
User entered '10 Sep 2020 18:35'	System	10 Sep 2020 23:36:03

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:51:06**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

**US3272085**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:06**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 16:19:14

US3272085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 16:19:14



US3272085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Sep 2020 16:19:14

US3272085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 16:19:14

US3272085

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 16:19:16

**US3272085**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:06**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Sep 2020 16:19:16

**US3272085**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:06**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 23:06:56

US3272085

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 23:06:56

**US3272085**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:06**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	18 Sep 2020 23:06:56

**US3272085**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:06**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 23:06:56



US3272085

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 23:06:59

**US3272085**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:06**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Sep 2020 23:06:59

**US3272085**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:06**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 16:55:02

**US3272085**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:06**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 16:55:02

US3272085

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	26 Sep 2020 16:55:02

**US3272085**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:06**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 16:55:02

US3272085

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 16:54:51

**US3272085**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:06**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Sep 2020 16:54:51



US3272085

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 20:44:20

US3272085

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '2 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 20:44:20

US3272085

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:51:06

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	02 Oct 2020 20:44:20

**US3272085**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:51:06**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	02 Oct 2020 20:44:20

US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 20:45:39

US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 20:45:39

US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User entered '14:03'	(b) (4), (b) (6)	02 Oct 2020 20:45:39

**US3272085**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:06**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '2 Oct 2020 14:03'	System	02 Oct 2020 20:45:39



US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.6' C	(b) (4), (b) (6)	02 Oct 2020 20:45:39

US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	02 Oct 2020 20:45:39

US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:45:39

US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '74'	(b) (4), (b) (6)	02 Oct 2020 20:45:39

**US3272085**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:51:06**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Oct 2020 20:45:39

US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	02 Oct 2020 20:45:39

US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Oct 2020 20:45:39

US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '132'	(b) (4), (b) (6)	02 Oct 2020 20:45:39



US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 20:45:39

US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '72'	(b) (4), (b) (6)	02 Oct 2020 20:45:39

US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:51:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 20:45:39

US3272085

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:06

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 20:45:53

US3272085

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:51:06

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 20:45:53

US3272085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 20:46:35

US3272085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 20:46:35

US3272085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:51:06

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '14:14'	(b) (4), (b) (6)	02 Oct 2020 20:46:35



**US3272085**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:51:06**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '2 Oct 2020 14:14'	System	02 Oct 2020 20:46:35

US3272085

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 20:46:42

**US3272085**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:06**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Oct 2020 20:46:42

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 64'	System	07 Aug 2020 22:16:40

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[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 (a5a7983321c3e006)', Time: '2020-10-07T00:01:51', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '03beed67-fedd-4d1e-829c-763c8b729163'	System	07 Oct 2020 05:02:58
User entered 'Yes (Y)'	System	07 Oct 2020 05:02:58

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Have you been exposed to someone with 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 (a5a7983321c3e006)', Time: '2020-10-07T00:02:33', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '03beed67-fedd-4d1e-829c-763c8b729163'	System	07 Oct 2020 05:02:58
User entered 'No (N)'	System	07 Oct 2020 05:02:58

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[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 (a5a7983321c3e006)', Time: '2020-10-07T00:02:39', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '03beed67-fedd-4d1e-829c-763c8b729163'	System	07 Oct 2020 05:02:58
User entered 'No (N)'	System	07 Oct 2020 05:02:58

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[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 (a5a7983321c3e006)', Time: '2020-10-07T00:02:47', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '03beed67-feddd4d1e-829c-763c8b729163'	System	07 Oct 2020 05:02:58
User entered 'No (N)'	System	07 Oct 2020 05:02:58



**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-10-07T00:02:56', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '03beed67-fedd-4d1e-829c-763c8b729163'	System	07 Oct 2020 05:02:58
User entered '07 Oct 2020 00:02:56'	System	07 Oct 2020 05:02:58

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered '07 Oct 2020 00:01'	System	07 Aug 2020 22:16:40

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered '11 Oct 2020 23:59'	System	07 Aug 2020 22:16:40

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 71'	System	07 Aug 2020 22:16:40

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[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 (a5a7983321c3e006)', Time: '2020-10-14T09:28:59', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '6497f34a-657d-4e73-ab3c-ae4905704913'	System	14 Oct 2020 14:29:49
User entered 'Yes (Y)'	System	14 Oct 2020 14:29:49

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

Have you been exposed to someone with 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 (a5a7983321c3e006)', Time: '2020-10-14T09:29:05', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '6497f34a-657d-4e73-ab3c-ae4905704913'	System	14 Oct 2020 14:29:49
User entered 'No (N)'	System	14 Oct 2020 14:29:49

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[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 (a5a7983321c3e006)', Time: '2020-10-14T09:29:12', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '6497f34a-657d-4e73-ab3c-ae4905704913'	System	14 Oct 2020 14:29:49
User entered 'No (N)'	System	14 Oct 2020 14:29:49

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[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 (a5a7983321c3e006)', Time: '2020-10-14T09:29:23', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '6497f34a-657d-4e73-ab3c-ae4905704913'	System	14 Oct 2020 14:29:49
User entered 'Yes (Y)'	System	14 Oct 2020 14:29:49



**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

Please 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 (a5a7983321c3e006)', Time: '2020-10-14T09:29:31', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '6497f34a-657d-4e73-ab3c-ae4905704913'	System	14 Oct 2020 14:29:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Oct 2020 14:29:49

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-10-14T09:29:39', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '6497f34a-657d-4e73-ab3c-ae4905704913'	System	14 Oct 2020 14:29:49
User entered '14 Oct 2020 09:29:39'	System	14 Oct 2020 14:29:49

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered '14 Oct 2020 00:01'	System	07 Aug 2020 22:16:40

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered '18 Oct 2020 23:59'	System	07 Aug 2020 22:16:40

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 78'	System	07 Aug 2020 22:16:40

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[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 (a5a7983321c3e006)', Time: '2020-10-21T02:37:19', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'f1526a96-0639-427e-b5f1-4011175240e0'	System	21 Oct 2020 07:38:35
User entered 'Yes (Y)'	System	21 Oct 2020 07:38:35

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

Have you been exposed to someone with 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 (a5a7983321c3e006)', Time: '2020-10-21T02:37:53', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'f1526a96-0639-427e-b5f1-4011175240e0'	System	21 Oct 2020 07:38:35
User entered 'No (N)'	System	21 Oct 2020 07:38:35

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[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 (a5a7983321c3e006)', Time: '2020-10-21T02:38:00', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'f1526a96-0639-427e-b5f1-4011175240e0'	System	21 Oct 2020 07:38:35
User entered 'No (N)'	System	21 Oct 2020 07:38:35



**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[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 (a5a7983321c3e006)', Time: '2020-10-21T02:38:17', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'f1526a96-0639-427e-b5f1-4011175240e0'	System	21 Oct 2020 07:38:35
User entered 'No (N)'	System	21 Oct 2020 07:38:35

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-10-21T02:38:31', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'f1526a96-0639-427e-b5f1-4011175240e0' User entered '21 Oct 2020 02:38:31'	System	21 Oct 2020 07:38:35
	System	21 Oct 2020 07:38:35

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered '21 Oct 2020 00:01'	System	07 Aug 2020 22:16:40

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered '25 Oct 2020 23:59'	System	07 Aug 2020 22:16:40

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 92'	System	07 Aug 2020 22:16:40

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[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 (a5a7983321c3e006)', Time: '2020-11-04T00:07:24', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '114129da-bdea-4c65-92eb-f94302f8041e'	System	04 Nov 2020 06:07:39
User entered 'No (N)'	System	04 Nov 2020 06:07:39

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

Have you been exposed to someone with 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 (a5a7983321c3e006)', Time: '2020-11-04T00:07:29', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '114129da-bdea-4c65-92eb-f94302f8041e'	System	04 Nov 2020 06:07:39
User entered 'No (N)'	System	04 Nov 2020 06:07:39

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-11-04T00:07:35', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '114129da-bdea-4c65-92eb-f94302f8041e'	System	04 Nov 2020 06:07:39
User entered '04 Nov 2020 00:07:35'	System	04 Nov 2020 06:07:39



**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered '04 Nov 2020 00:01'	System	07 Aug 2020 22:16:40

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered '08 Nov 2020 23:59'	System	07 Aug 2020 22:16:40

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 99'	System	07 Aug 2020 22:16:40

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[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 (a5a7983321c3e006)', Time: '2020-11-11T10:02:41', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'c95e32b9-6bc2-4e4f-96a0-7913e6a4e696'	System	11 Nov 2020 16:03:18
User entered 'No (N)'	System	11 Nov 2020 16:03:18

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

Have you been exposed to someone with 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 (a5a7983321c3e006)', Time: '2020-11-11T10:02:51', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'c95e32b9-6bc2-4e4f-96a0-7913e6a4e696'	System	11 Nov 2020 16:03:18
User entered 'Yes (Y)'	System	11 Nov 2020 16:03:18

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Please 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 (a5a7983321c3e006)', Time: '2020-11-11T10:02:58', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'c95e32b9-6bc2-4e4f-96a0-7913e6a4e696'	System	11 Nov 2020 16:03:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Nov 2020 16:03:18

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-11-11T10:03:02', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'c95e32b9-6bc2-4e4f-96a0-7913e6a4e696'	System	11 Nov 2020 16:03:18
User entered '11 Nov 2020 10:03:02'	System	11 Nov 2020 16:03:18

**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered '11 Nov 2020 00:01'	System	07 Aug 2020 22:16:40



**US3272085**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Aug 2020 22:16:40
User entered '15 Nov 2020 23:59'	System	07 Aug 2020 22:16:40

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '04 Oct 2020 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '08 Oct 2020 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '11 Oct 2020 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '15 Oct 2020 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '18 Oct 2020 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '22 Oct 2020 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '25 Oct 2020 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '29 Oct 2020 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '01 Nov 2020 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '05 Nov 2020 23:59'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '08 Nov 2020 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '12 Nov 2020 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '15 Nov 2020 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '19 Nov 2020 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 16:21:32



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 16:21:32



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 16:21:32



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 16:21:32



**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:51:06**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 16:21:32

**US3272085**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:06**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 13:28:44



US3272085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 13:28:44

US3272085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:51:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Oct 2020 13:28:44

**US3272085**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:51:06**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 13:28:44

US3272085

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:51:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 13:28:50

**US3272085**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:51:06**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Oct 2020 13:28:50

US3272085

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:51:06

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bell (b) (4)	15 Oct 2020 16:24:20
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 13:56:19

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:06**

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:13
User entered 'USA-US070-2020-mRNA-1273-P301000006'	System	16 Oct 2020 00:29:10
User entered 'New'	(b) (4), (b) (6)	16 Oct 2020 00:29:10

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 19:06:56
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal chest pain, LLT: Chest wall pain - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 16:35:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 16:35:20
Data point term sent to Coder	System	02 Nov 2020 21:30:37
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4)	02 Nov 2020 21:30:08
Coding entries removed.	Kayla Flege (b) (4)	02 Nov 2020 21:29:50
Signature has been broken.	Kayla Flege (b) (4)	02 Nov 2020 21:29:50
User entered 'WORSENING INTERMITTENT CHEST WALL PAIN Non Cardiac' reason for change: Data Entry Error	Kayla Flege (b) (4)	02 Nov 2020 21:29:50
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 06:28:00



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal chest pain, LLT: Chest wall pain - version MedDRA\\23.0.	Coder Import (b) (4)	16 Oct 2020 00:16:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Oct 2020 00:16:40
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
Data point term sent to Coder	System	15 Oct 2020 16:40:39
User entered 'Worsening Intermittent chest wall pain'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered 'Yes (Y)'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered 'No (N)'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered 'No (N)'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Signature has been broken.	Kayla Flege (b) (4)	19 Nov 2020 19:48:11
	(b) (4)	
User entered '07 Oct 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	19 Nov 2020 19:48:11
	(b) (4)	
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered '7 Oct 2020'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21
	(b) (4)	

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered empty.	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:06**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 16:40:21

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered 'Yes (Y)'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21



US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:46:52
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available. ' answered with 'left message for pt' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	19 Nov 2020 19:52:43
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 13:50:02
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 13:50:02
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'not yet available' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 22:50:04
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 13:09:48
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 16:48:10
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'ongoing no end date' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 20:14:59
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 19:13:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered empty.	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:06**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered empty.	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:06**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 16:40:21

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered 'Grade 3/Severe (Grade 3/Severe)'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered 'Yes (Y)'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered '0'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered '0'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21



**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered '1'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered '9 Oct 2020'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered '10 Oct 2020'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered 'No (N)'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered empty.	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered '0'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered '0'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered '0'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21



**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered 'Not Related (NOT RELATED)'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered 'Not Related (NOT RELATED)'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'PV Query: As the last dose of mRNA-1273 or placebo was given on 04 Sep 2020, please update the action taken with mRNA-1273 or placebo from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 16:48:16
Query 'PV Query: As the last dose of mRNA-1273 or placebo was given on 04 Sep 2020, please update the action taken with mRNA-1273 or placebo from none to not applicable.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 20:15:23
Signature has been broken.	(b) (4), (b) (6)	28 Oct 2020 20:15:15
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 20:15:15
User opened query 'PV Query: As the last dose of mRNA-1273 or placebo was given on 04 Sep 2020, please update the action taken with mRNA-1273 or placebo from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 19:13:39
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered 'None (NONE)'	Andrea Clement (b) (4) (b) (4)	15 Oct 2020 16:40:21

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:06**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered '0'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered '1'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered '0'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. Please leave query open until resolution is obtained or the subject reaches a new baseline. ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:46:56
Query 'PV Query: Please provide the final event outcome, when available. Please leave query open until resolution is obtained or the subject reaches a new baseline. ' answered with 'left message for pt' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	19 Nov 2020 19:52:30
User opened query 'PV Query: Please provide the final event outcome, when available. Please leave query open until resolution is obtained or the subject reaches a new baseline. ' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 13:50:51
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 13:50:51
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'still ongoing ' (Site from Safety).	Ashley Bell (b) (4)	15 Nov 2020 20:35:10
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 13:09:56
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 16:48:24
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'not resolved yet' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 20:15:38

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 19:14:12
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21



**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:06**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered empty.	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR - RQ: Site's response noted. However, please ensure that this blood work up is recorded in the ConProc eCRF. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 17:56:22
Query 'Per DM CLR - RQ: Site's response noted. However, please ensure that this blood work up is recorded in the ConProc eCRF. Update eCRF as appropriate. ' answered with 'Left message for patient to return call for more information. Will update when patient calls back.' (Site from DM).	Kayla Flege (b) (4) (b) (4)	23 Nov 2020 20:03:29
User opened query 'Per DM CLR - RQ: Site's response noted. However, please ensure that this blood work up is recorded in the ConProc eCRF. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 08:50:37
User closed query 'Per DM CLR: SAE Narrative = HE STATES CARDIAC ENZYMES WERE NORMAL. However, please confirm if this needs to be recorded in the ConProc eCRF. If yes, please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 08:50:37
Query 'Per DM CLR: SAE Narrative = HE STATES CARDIAC ENZYMES WERE NORMAL. However, please confirm if this needs to be recorded in the ConProc eCRF. If yes, please review and ensure that this is captured in the appropriate eCRF. ' answered with 'There were no procedures. Only lab drawn.' (Site from DM).	Kayla Flege (b) (4) (b) (4)	02 Nov 2020 21:31:31
User opened query 'Per DM CLR: SAE Narrative = HE STATES CARDIAC ENZYMES WERE NORMAL. However, please confirm if this needs to be recorded in the ConProc eCRF. If yes, please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 06:28:14
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. ?If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 16:48:30

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:51:06

[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 'not done' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 20:16:06
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 Oct 2020 19:14:39
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered 'States on 14OCT2020 that he started with mild chest pain on Wednesday 07OCT2020 he woke up with mild chest pain, diaphoresis, and some nausea. He states by Friday, 09OCT2020 the chest pain was worsening and he went to the ER. He was then admitted to the Hospital for a 24 hour observation to R/O Acute Coronary Syndrome, and Pericarditis. Diagnosis from Hospital was Chest Wall Pain. He states cardiac enzymes were normal and he was discharged from the hospital on 10OCT2020. He then saw his PCP on 14OCT2020 due to continued chest pain. PCP states this is intermittent chest wall pain that is worsening and patient was given a script for Hydrocodone/APAP 5/325 mg and Cholchicine 0.6mg.'	Andrea Clement (b) (4) (b) (4)	15 Oct 2020 16:40:21

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Oct 2020 16:40:21

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Oct 2020 16:40:21

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Nov 2020 20:36:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Nov 2020 20:36:48
Data point term sent to Coder	System	15 Nov 2020 20:36:09
User entered 'Cough'	Ashley Bell (b) (4) (b) (4)	15 Nov 2020 20:35:45

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ashley Bell (b) (4) [REDACTED]	15 Nov 2020 20:35:45



US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '05 Nov 2020'	Ashley Bell (b) (4) [REDACTED]	15 Nov 2020 20:35:45

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Ashley Bell (b) (4) [REDACTED]	15 Nov 2020 20:35:45

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:06**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Nov 2020 20:35:45

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ashley Bell (b) (4) [REDACTED]	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Ashley Bell (b) (4) [REDACTED]	15 Nov 2020 20:35:45

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:06**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Ashley Bell (b) (4) [REDACTED]	15 Nov 2020 20:35:45



**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:06**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Nov 2020 20:35:45

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Ashley Bell (b) (4) [REDACTED]	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Ashley Bell (b) (4) [REDACTED]	15 Nov 2020 20:35:45

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Ashley Bell (b) (4) [REDACTED]	15 Nov 2020 20:35:45

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Ashley Bell (b) (4) [REDACTED]	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Ashley Bell (b) (4)	15 Nov 2020 20:35:45



**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Ashley Bell (b) (4) [REDACTED]	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Ashley Bell (b) (4) [REDACTED]	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Ashley Bell (b) (4) [REDACTED]	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Ashley Bell (b) (4) [REDACTED]	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Ashley Bell (b) (4) [REDACTED]	15 Nov 2020 20:35:45



**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:06**

[None](#)

Audit	User	Time (GMT)
User entered 'I'	Ashley Bell (b) (4) [REDACTED]	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Ashley Bell (b) (4) [REDACTED]	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:51:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Ashley Bell (b) (4) [REDACTED]	15 Nov 2020 20:35:45

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:06**

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Ashley Bell (b) (4) [REDACTED]	15 Nov 2020 20:35:45

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Nov 2020 20:35:45

**US3272085**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Nov 2020 20:35:45



US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 26 Nov 2020 10:51:06**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:40:24

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 12:44:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 12:44:11
Data point term sent to Coder	System	10 Aug 2020 12:43:51
User entered 'Metformin'	(b) (4), (b) (6)	10 Aug 2020 12:43:35

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 13:57:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 13:57:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 13:57:03
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 12:43:35
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:43:35

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Diabetes'	(b) (4), (b) (6)	10 Aug 2020 12:43:35

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1000'	(b) (4), (b) (6)	10 Aug 2020 12:43:35

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Aug 2020 12:43:35

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:06**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:43:35

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Aug 2020 12:43:35



US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:06**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:43:35

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Aug 2020 12:43:35

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:06**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:43:35

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:51:06

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)	13 Aug 2020 19:43:18
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)	11 Aug 2020 13:57:00
answered with 'required per protocol' (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	10 Aug 2020 12:43:35
User entered 'un UNK 2007'	(b) (4), (b) (6)	10 Aug 2020 12:43:35

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 12:43:35

**US3272085**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:43:35

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:06**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:43:35

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:43:35



**US3272085**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:43:35

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:43:35

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 12:43:35

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 23:54:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 23:54:45
Data point term sent to Coder	System	21 Sep 2020 23:53:54
Coding entries removed.	(b) (4), (b) (6)	21 Sep 2020 23:53:07
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 12:46:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 12:46:11
Data point term sent to Coder	System	10 Aug 2020 12:45:53
User entered 'Meloxicam'	(b) (4), (b) (6)	10 Aug 2020 12:45:37

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:45:37

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:06

[Indication](#)

Audit	User	Time (GMT)
Query 'Per CDM: Please update and provide location of 'OSTEOARTHRITIS' (e.g. Knees, Elbows, Hips, etc.). Please ensure that there is a corresponding MH/AE record that match the updated indication. Please update applicable details as appropriate or provide further clarification.' answered with 'all over body' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 22:51:50
User opened query 'Per CDM: Please update and provide location of 'OSTEOARTHRITIS' (e.g. Knees, Elbows, Hips, etc.). Please ensure that there is a corresponding MH/AE record that match the updated indication. Please update applicable details as appropriate or provide further clarification.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 22:01:15
User closed query 'Per DM CLR: Please review Indication and please update to specify the type of Arthritis (e.g. Osteoarthritis, Rheumatoid, etc.). Please update and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:46:10
Query 'Per DM CLR: Please review Indication and please update to specify the type of Arthritis (e.g. Osteoarthritis, Rheumatoid, etc.). Please update and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 23:53:46
User entered 'osteoARTHRITIS' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 23:53:07
User opened query 'Per DM CLR: Please review Indication and please update to specify the type of Arthritis (e.g. Osteoarthritis, Rheumatoid, etc.). Please update and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 06:06:25
User entered 'Generalized Arthritis'	(b) (4), (b) (6)	10 Aug 2020 12:45:37

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '15'	(b) (4), (b) (6)	10 Aug 2020 12:45:37

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Aug 2020 12:45:37



US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:06**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:45:37

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Aug 2020 12:45:37

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:06**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:45:37

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Aug 2020 12:45:37

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:06**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:45:37

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:51:06

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)	13 Aug 2020 19:41:55
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)	11 Aug 2020 13:57:12
answered with 'required per protocol' (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	10 Aug 2020 12:45:37
User entered 'un UNK 2010'	(b) (4), (b) (6)	10 Aug 2020 12:45:37

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 12:45:37

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:45:37



US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:06**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:45:37

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:45:37

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:45:37

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:45:37

**US3272085**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 12:45:37

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 12:48:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 12:48:17
Data point term sent to Coder	System	10 Aug 2020 12:47:53
User entered 'Losartan'	(b) (4), (b) (6)	10 Aug 2020 12:46:58

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:06**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:46:58

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:06**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypertension'	(b) (4), (b) (6)	10 Aug 2020 12:46:58



US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:06**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	(b) (4), (b) (6)	10 Aug 2020 12:46:58

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:06**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Aug 2020 12:46:58

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:06**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:46:58

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:06**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Aug 2020 12:46:58

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:06**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:46:58

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:06**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Aug 2020 12:46:58

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:06**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:46:58

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:51:06

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)	13 Aug 2020 19:41:56
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)	11 Aug 2020 13:57:17
answered with 'required per protocol' (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	10 Aug 2020 12:46:58
User entered 'un UNK 2010'	(b) (4), (b) (6)	10 Aug 2020 12:46:58



US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:06**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 12:46:58

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:06**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:46:58

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:06**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:46:58

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:06**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:46:58

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:06**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:46:58

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:06**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:46:58

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:51:06**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 12:46:58

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: THIAZOLIDINEDIONES, PRODUCT: PIOGLITAZONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 17:39:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 17:39:14
Data point term sent to Coder	System	10 Aug 2020 12:48:54
User entered 'Pioglitazone'	(b) (4), (b) (6) (b) (4)	10 Aug 2020 12:48:26



US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:06**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:48:26

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:06**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Type 2 diabetes'	(b) (4), (b) (6)	10 Aug 2020 12:48:26

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:06**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '30'	(b) (4), (b) (6)	10 Aug 2020 12:48:26

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:06**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Aug 2020 12:48:26

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:06**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:48:26

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:06**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Aug 2020 12:48:26

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:06**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:48:26

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:06**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Aug 2020 12:48:26



US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:06**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:48:26

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:51:06

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)	13 Aug 2020 19:41:57
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)	11 Aug 2020 13:57:23
answered with 'required per protocol' (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	10 Aug 2020 12:48:26
User entered 'un UNK 2010'	(b) (4), (b) (6)	10 Aug 2020 12:48:26

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:06**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 12:48:26

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:06**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:48:26

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:06**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:48:26

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:06**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:48:26

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:06**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:48:26

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:06**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:48:26



US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:51:06**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 12:48:26

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 12:51:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 12:51:54
Data point term sent to Coder	System	10 Aug 2020 12:49:54
User entered 'Atorvastatin'	(b) (4), (b) (6)	10 Aug 2020 12:49:25

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:51:06**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:49:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:06

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypercholesterolemia'	(b) (4), (b) (6)	10 Aug 2020 12:49:25

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:51:06**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	(b) (4), (b) (6)	10 Aug 2020 12:49:25

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:51:06**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Aug 2020 12:49:25

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:51:06**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:49:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'every other day (QOD)' reason for change: Data Entry Error	Ashley Bell (b) (4)	15 Oct 2020 16:03:54
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Aug 2020 12:49:25



US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:51:06**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:49:25

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:51:06**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Aug 2020 12:49:25

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:51:06**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:49:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:06

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)	13 Aug 2020 19:41:58
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)	11 Aug 2020 13:57:28
answered with 'required per protocol' (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	10 Aug 2020 12:49:25
User entered 'un UNK 2012'	(b) (4), (b) (6)	10 Aug 2020 12:49:25

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:51:06**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 12:49:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:51:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:49:25

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:51:06**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:49:25

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:51:06**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:49:25



US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:51:06**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:49:25

**US3272085**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:51:06**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Oct 2020 16:03:54
User entered '1'	System	10 Aug 2020 12:49:25

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:51:06**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 12:49:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 12:53:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 12:53:12
Data point term sent to Coder	System	10 Aug 2020 12:51:55
User entered 'Hydrochlorothiazide'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Aug 2020 12:51:14

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:06**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:51:14

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:06**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypertension'	(b) (4), (b) (6)	10 Aug 2020 12:51:14

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:06**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '12.5'	(b) (4), (b) (6)	10 Aug 2020 12:51:14

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:06**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Aug 2020 12:51:14



US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:06**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:51:14

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:06**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Aug 2020 12:51:14

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:06**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:51:14

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:06**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Aug 2020 12:51:14

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:06**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:51:14

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:51:06

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)	13 Aug 2020 19:41:59
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)	11 Aug 2020 13:57:33
answered with 'required per protocol' (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	10 Aug 2020 12:51:14
User entered 'un UNK 2019'	(b) (4), (b) (6)	10 Aug 2020 12:51:14

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:06**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 12:51:14

**US3272085**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:06**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:51:14



US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:06**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:51:14

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:06**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:51:14

**US3272085**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:06**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:51:14

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:06**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:51:14

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:51:06**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 12:51:14

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:06

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN LOW - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 23:55:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 23:55:46
Data point term sent to Coder	System	21 Sep 2020 23:54:57
Coding entries removed.	(b) (4), (b) (6)	21 Sep 2020 23:54:19
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN LOW - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 15:09:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 15:09:47
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:49:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:49:19
Data point term sent to Coder	System	10 Aug 2020 12:54:59
User entered 'Low dose aspirin'	(b) (4), (b) (6)	10 Aug 2020 12:54:27

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 23:54:33
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:54:27

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:06

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review Indication and please update to add/include the medical condition that this medication was used to prevent. Please also update Prophylaxis to YES accordingly. Please update applicable details as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 19:03:37
Query 'Per DM CLR: Please review Indication and please update to add/include the medical condition that this medication was used to prevent. Please also update Prophylaxis to YES accordingly. Please update applicable details as appropriate or provide clarification. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 23:54:27
User entered 'cardiac prophylaxis' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 23:54:19
User opened query 'Per DM CLR: Please review Indication and please update to add/include the medical condition that this medication was used to prevent. Please also update Prophylaxis to YES accordingly. Please update applicable details as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 06:05:57
User entered 'Preventative'	(b) (4), (b) (6)	10 Aug 2020 12:54:27



US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:51:06**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '81'	(b) (4), (b) (6)	10 Aug 2020 12:54:27

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:51:06**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Aug 2020 12:54:27

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:51:06**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:54:27

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Aug 2020 12:54:27

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:51:06**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:54:27

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:51:06**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Aug 2020 12:54:27

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:51:06**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:54:27

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:51:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 2013' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 23:13:32
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)	13 Aug 2020 19:42:00
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)	11 Aug 2020 13:57:38
answered with 'required per protocol' (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	10 Aug 2020 12:54:27
User entered 'un UNK 2015'	(b) (4), (b) (6)	10 Aug 2020 12:54:27



US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:51:06**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 12:54:27

**US3272085**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:51:06**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:54:27

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:51:06**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:54:27

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:51:06**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:54:27

**US3272085**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:51:06**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:54:27

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:51:06**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:54:27

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:51:06**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 12:54:27

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:51:06

[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: NEBIVOLOL HYDROCHLORIDE, PRODUCTSYNONYM: BYSTOLIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 23:56:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 23:56:47
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	21 Sep 2020 23:55:57 21 Sep 2020 23:55:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: NEBIVOLOL HYDROCHLORIDE, PRODUCTSYNONYM: BYSTOLIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 12:58:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 12:58:21
Data point term sent to Coder User entered 'Bystolic'	System (b) (4), (b) (6)	10 Aug 2020 12:57:01 10 Aug 2020 12:56:59



US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:06**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:56:59

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:51:06

[Indication](#)

Audit	User	Time (GMT)
Query 'Per CDM: There is no corresponding Medical History record that match this condition. Kindly review and update as appropriately.' canceled (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:51:03
User opened query 'Per CDM: There is no corresponding Medical History record that match this condition. Kindly review and update as appropriately.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:50:46
User closed query 'Per DM CLR: Indication of Cardiac Prophylaxis was noted, however, there is a recorded MH condition of Hypertension that match this medication. Please verify if this was given as treatment for the MH condition and update accordingly. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:50:46
Query 'Per DM CLR: Indication of Cardiac Prophylaxis was noted, however, there is a recorded MH condition of Hypertension that match this medication. Please verify if this was given as treatment for the MH condition and update accordingly. Otherwise, clarify. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 23:55:41
User entered 'hypertension' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 23:55:35
User opened query 'Per DM CLR: Indication of Cardiac Prophylaxis was noted, however, there is a recorded MH condition of Hypertension that match this medication. Please verify if this was given as treatment for the MH condition and update accordingly. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 06:04:39
User entered 'Cardiac Prophylaxis'	(b) (4), (b) (6)	10 Aug 2020 12:56:59

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:06**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5'	(b) (4), (b) (6)	10 Aug 2020 12:56:59

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:06**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Aug 2020 12:56:59

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:06**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:56:59

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:51:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Aug 2020 12:56:59

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:06**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:56:59

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:06**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Aug 2020 12:56:59



US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:06**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:56:59

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:51:06

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)	13 Aug 2020 19:42:01
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)	11 Aug 2020 13:57:43
answered with 'required per protocol' (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	10 Aug 2020 12:56:59
User entered 'un UNK 2013'	(b) (4), (b) (6)	10 Aug 2020 12:56:59

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:06**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 12:56:59

**US3272085**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:06**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:56:59

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:06**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:56:59

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:06**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:56:59

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:06**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:56:59

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:06**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:56:59



US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:51:06**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 12:56:59

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:06

[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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 23:57:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 23:57:49
Data point term sent to Coder	System	21 Sep 2020 23:57:06
Coding entries removed.	(b) (4), (b) (6)	21 Sep 2020 23:56:16
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 17:35:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 17:35:25
Data point term sent to Coder	System	10 Aug 2020 12:58:01
User entered 'Omeprazole'	(b) (4), (b) (6)	10 Aug 2020 12:57:55

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:51:06**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:57:55

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:06

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Indication of Preventative was noted, however, there is a recorded MH condition of Gastroesophageal Reflux Disease that match this medication. Please verify if this was given as treatment for the MH condition and update accordingly. Otherwise, update to add/include the medical condition this medication was used to prevent. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:52:32
Query 'Per DM CLR: Indication of Preventative was noted, however, there is a recorded MH condition of Gastroesophageal Reflux Disease that match this medication. Please verify if this was given as treatment for the MH condition and update accordingly. Otherwise, update to add/include the medical condition this medication was used to prevent. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 23:56:22
User entered 'gastroesophageal reflux disease' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 23:56:16
User opened query 'Per DM CLR: Indication of Preventative was noted, however, there is a recorded MH condition of Gastroesophageal Reflux Disease that match this medication. Please verify if this was given as treatment for the MH condition and update accordingly. Otherwise, update to add/include the medical condition this medication was used to prevent. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 06:06:47
User entered 'Preventative'	(b) (4), (b) (6)	10 Aug 2020 12:57:55

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40' reason for change: New Information	(b) (4), (b) (6)	10 Aug 2020 13:01:04
User entered '1'	(b) (4), (b) (6)	10 Aug 2020 12:57:55

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:51:06**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Aug 2020 12:57:55

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:51:06**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:57:55

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)' reason for change:	Ashley Bell (b) (4)	15 Oct 2020 16:04:12
Data Entry Error		
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Aug 2020 12:57:55



US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:51:06**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:57:55

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:51:06**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Aug 2020 12:57:55

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:51:06**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:57:55

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:06

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)	13 Aug 2020 19:42:02
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)	11 Aug 2020 13:57:48
answered with 'required per protocol' (Site from System).		
User entered 'UN UNK 2009' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 13:01:04
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	10 Aug 2020 12:57:55
User entered 'un UNK 2015'	(b) (4), (b) (6)	10 Aug 2020 12:57:55

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:51:06**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 12:57:55

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:51:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:57:55

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:51:06**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:57:55

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:51:06**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:57:55



US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:51:06**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Oct 2020 16:04:12
User entered '1'	System	10 Aug 2020 12:57:55

**US3272085**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:51:06**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:57:55

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:51:06**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 12:57:55

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:06

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: BILE ACID SEQUESTRANTS, PRODUCT: COLESTIPOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 21:32:43
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 21:32:43
Data point term sent to Coder Coding entries removed.	System Ashley Bell (b) (4)	15 Oct 2020 16:07:19 15 Oct 2020 16:06:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: BILE ACID SEQUESTRANTS, PRODUCT: COLESTIPOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 23:57:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 23:57:49
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	21 Sep 2020 23:57:06 21 Sep 2020 23:56:46
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: BILE ACID SEQUESTRANTS, PRODUCT: COLESTIPOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 23:41:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 23:41:12
Data point term sent to Coder Data point term sent to Coder User entered 'Colestipol'	System System (b) (4), (b) (6)	10 Aug 2020 13:03:08 10 Aug 2020 13:02:06 10 Aug 2020 13:01:46

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:51:06**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 13:01:46

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:06

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Indication of Preventative was noted, however, there is a recorded MH condition of Hypercholesterolemia that match this medication. Please verify if this was given as treatment for the MH condition and update accordingly. Otherwise, update to add/include the medical condition this medication was used to prevent. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:52:01
User entered 'Diarrhea' reason for change: Data Entry Error	Ashley Bell (b) (4)	15 Oct 2020 16:06:36
Query 'Per DM CLR: Indication of Preventative was noted, however, there is a recorded MH condition of Hypercholesterolemia that match this medication. Please verify if this was given as treatment for the MH condition and update accordingly. Otherwise, update to add/include the medical condition this medication was used to prevent. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 23:57:24
User entered 'hypercholesterolemia' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 23:56:46
User opened query 'Per DM CLR: Indication of Preventative was noted, however, there is a recorded MH condition of Hypercholesterolemia that match this medication. Please verify if this was given as treatment for the MH condition and update accordingly. Otherwise, update to add/include the medical condition this medication was used to prevent. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 06:05:11
User entered 'Preventative'	(b) (4), (b) (6)	10 Aug 2020 13:01:46

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:51:06**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	10 Aug 2020 13:01:46

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:06

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'g (g)' reason for change: Data Entry Error	Ashley Bell (b) (4)	15 Oct 2020 16:05:27
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Aug 2020 13:01:46



US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:51:06**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 13:01:46

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)' reason for change:	Ashley Bell (b) (4)	15 Oct 2020 16:05:27
Data Entry Error		
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Aug 2020 13:01:46

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:51:06**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 13:01:46

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:06

[Route of administration](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 13:02:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 13:02:21
User entered 'Oral (ORAL)' reason for change: New Information	(b) (4), (b) (6)	10 Aug 2020 13:02:21
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 13:01:46
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 13:01:46

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:51:06**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 13:01:46

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:51:06

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)	13 Aug 2020 19:42:07
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)	11 Aug 2020 13:57:55
answered with 'required per protocol' (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	10 Aug 2020 13:01:46
User entered 'un UNK 2015'	(b) (4), (b) (6)	10 Aug 2020 13:01:46

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:51:06**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 13:01:46

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:51:06**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 13:01:46



US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:51:06**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 13:01:46

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:51:06**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 13:01:46

**US3272085**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:51:06**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 16:05:27
User entered '1'	System	10 Aug 2020 13:01:46

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:51:06**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 16:05:27
User entered '1'	System	10 Aug 2020 13:01:46

**US3272085**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:51:06**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 16:05:27
User entered '804 (804)'	System	10 Aug 2020 13:01:46

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:51:06

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/APAP - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 16:31:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 16:31:27
Data point term sent to Coder Coding entries removed.	System	15 Oct 2020 16:30:11
	Ashley Bell (b) (4)	15 Oct 2020 16:30:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/APAP - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 16:15:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 16:15:27
Data point term sent to Coder User entered 'hydrocodone/apap'	System	15 Oct 2020 16:14:36
	Ashley Bell (b) (4)	15 Oct 2020 16:14:21

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:06**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Ashley Bell (b) (4) [REDACTED]	15 Oct 2020 16:14:21

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:51:06

[Indication](#)

Audit	User	Time (GMT)
User entered 'WORSENING intermittent CHEST WALL PAIN' reason for change: Data Entry Error	Ashley Bell (b) (4)	15 Oct 2020 16:30:05
User entered 'worsening chest wall pain'	Ashley Bell (b) (4)	15 Oct 2020 16:14:21



US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:06**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5/325'	Ashley Bell (b) (4) [REDACTED]	15 Oct 2020 16:14:21

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:51:06

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	15 Oct 2020 16:14:32
User entered 'Other (OTHER)' reason for change: Data Entry Error	Ashley Bell (b) (4)	15 Oct 2020 16:14:32
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	15 Oct 2020 16:14:21
User entered 'mg (mg)'	Ashley Bell (b) (4)	15 Oct 2020 16:14:21

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:06**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered '1-2 tablets max 10/650mg'	Ashley Bell (b) (4)	15 Oct 2020 16:14:21

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:06**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	Ashley Bell (b) (4) [REDACTED]	15 Oct 2020 16:14:21

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:06**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered 'every 4-6 as needed'	Ashley Bell (b) (4) [REDACTED]	15 Oct 2020 16:14:21

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:06**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Ashley Bell (b) (4)	15 Oct 2020 16:14:21

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:06**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Ashley Bell (b) (4)	15 Oct 2020 16:14:21

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:06**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	Ashley Bell (b) (4)	15 Oct 2020 16:14:21



US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:06**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Ashley Bell (b) (4) [REDACTED]	15 Oct 2020 16:14:21

**US3272085**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:06**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ashley Bell (b) (4) [REDACTED]	15 Oct 2020 16:14:21

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:06**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Ashley Bell (b) (4) [REDACTED]	15 Oct 2020 16:14:21

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:06**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Ashley Bell (b) (4) [REDACTED]	15 Oct 2020 16:14:21

**US3272085**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:06**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 16:14:21

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:06**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 16:14:21

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:51:06**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 16:14:21

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:51:06

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM, PRODUCT: COLCHICINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 21:26:08
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 21:26:08
Data point term sent to Coder Coding entries removed.	System Ashley Bell (b) (4)	15 Oct 2020 16:31:15 15 Oct 2020 16:30:18
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM, PRODUCT: COLCHICINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:28:42
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 16:28:42
Data point term sent to Coder User entered 'cholchicine'	System Ashley Bell (b) (4)	15 Oct 2020 16:15:38 15 Oct 2020 16:15:25



US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:06**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Ashley Bell (b) (4)	15 Oct 2020 16:15:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:51:06

[Indication](#)

Audit	User	Time (GMT)
User entered 'WORSENING intermittent CHEST WALL PAIN' reason for change: Data Entry Error	Ashley Bell (b) (4)	15 Oct 2020 16:30:18
User entered 'worsening chest wall pain'	Ashley Bell (b) (4)	15 Oct 2020 16:15:25

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:06**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.6'	Ashley Bell (b) (4) [REDACTED]	15 Oct 2020 16:15:25

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:06**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Ashley Bell (b) (4) [REDACTED]	15 Oct 2020 16:15:25

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:06**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Ashley Bell (b) (4)	15 Oct 2020 16:15:25

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:06**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Ashley Bell (b) (4)	15 Oct 2020 16:15:25

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:06**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Ashley Bell (b) (4) [REDACTED]	15 Oct 2020 16:15:25

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:06**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Ashley Bell (b) (4)	15 Oct 2020 16:15:25



US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:06**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Ashley Bell (b) (4) [REDACTED]	15 Oct 2020 16:15:25

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:06**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	Ashley Bell (b) (4) [REDACTED]	15 Oct 2020 16:15:25

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:06**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Ashley Bell (b) (4) [REDACTED]	15 Oct 2020 16:15:25

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:06**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ashley Bell (b) (4)	15 Oct 2020 16:15:25

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:06**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Ashley Bell (b) (4)	15 Oct 2020 16:15:25

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:06**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Ashley Bell (b) (4)	15 Oct 2020 16:15:25

**US3272085**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:06**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Oct 2020 16:15:25

US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:06**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 16:15:25



US3272085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:51:06**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 16:15:25

US3272085

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 10:51:06**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 13:56:28

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'USA-US070-2020-MRNA-1273-P301000006'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Yes (Y)'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Yes (Y)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10



US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Adam'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Brosz'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered '2444 W. Faidley Ave'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Grand Island'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'NE'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered '68803'	System	16 Oct 2020 00:29:10



**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:49:09
User entered 'US'	System	16 Oct 2020 00:29:32

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Nov 2020 15:43:24
User entered '3'	System	03 Nov 2020 14:31:40
User entered '2'	System	29 Oct 2020 16:50:28
User entered '1'	System	16 Oct 2020 00:29:32

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'USA-US070-2020-MRNA-1273-P301000006'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Yes (Y)'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Yes (Y)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10



US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Adam'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Brosz'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered '2444 W. Faidley Ave'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Grand Island'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'NE'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered '68803'	System	16 Oct 2020 00:29:10



**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:49:09
User entered 'US'	System	16 Oct 2020 00:29:32

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Nov 2020 15:43:24
User entered '3'	System	03 Nov 2020 14:31:40
User entered '2'	System	29 Oct 2020 16:50:28
User entered '1'	System	16 Oct 2020 00:29:32

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form (1)**

**Generated On: 26 Nov 2020 10:51:06**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '15/Oct/2020 20:29'	System	16 Oct 2020 00:29:32

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:51:06

**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)	29 Oct 2020 16:49:09
User entered 'I'	(b) (4), (b) (6)	16 Oct 2020 00:29:32

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'USA-US070-2020-MRNA-1273-P301000006'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Yes (Y)'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10



**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Yes (Y)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Adam'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Brosz'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered '2444 W. Faidley Ave'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Grand Island'	System	16 Oct 2020 00:29:10



**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'NE'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered '68803'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:49:09
User entered 'US'	System	16 Oct 2020 00:29:32

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Nov 2020 15:43:24
User entered '3'	System	03 Nov 2020 14:31:40
User entered '2'	System	29 Oct 2020 16:50:28
User entered '1'	System	16 Oct 2020 00:29:32

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form (2)**

**Generated On: 26 Nov 2020 10:51:06**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '29/Oct/2020 16:50'	System	29 Oct 2020 16:50:28

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:51:06

**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)	03 Nov 2020 14:31:10
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:50:28
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 16:50:28
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:49:09
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 00:29:32

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'USA-US070-2020-MRNA-1273-P301000006'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Yes (Y)'	System	16 Oct 2020 00:29:10



**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Yes (Y)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Adam'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Brosz'	System	16 Oct 2020 00:29:10



**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered '2444 W. Faidley Ave'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Grand Island'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'NE'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered '68803'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:49:09
User entered 'US'	System	16 Oct 2020 00:29:32

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Nov 2020 15:43:24
User entered '3'	System	03 Nov 2020 14:31:40
User entered '2'	System	29 Oct 2020 16:50:28
User entered '1'	System	16 Oct 2020 00:29:32

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form (3)**

**Generated On: 26 Nov 2020 10:51:06**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '03/Nov/2020 14:31'	System	03 Nov 2020 14:31:40

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:51:06

**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)	20 Nov 2020 15:43:13
Un-reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 14:31:40
User entered '1' reason for change: Obvious Correction	(b) (4), (b) (6)	03 Nov 2020 14:31:40
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 14:31:10
User entered '0'	(b) (4), (b) (6)	29 Oct 2020 16:50:28



**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'USA-US070-2020-MRNA-1273-P301000006'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Yes (Y)'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

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Generated On: 26 Nov 2020 10:51:06

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Yes (Y)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:51:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10



**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Adam'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Brosz'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered '2444 W. Faidley Ave'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Grand Island'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'NE'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered '68803'	System	16 Oct 2020 00:29:10

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:49:09
User entered 'US'	System	16 Oct 2020 00:29:32

**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:51:06**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Nov 2020 15:43:24
User entered '3'	System	03 Nov 2020 14:31:40
User entered '2'	System	29 Oct 2020 16:50:28
User entered '1'	System	16 Oct 2020 00:29:32



**US3272085**

**Folder: SAE USA-US070-2020-MRNA-1273-P301000006**

**Form: Safety Report Form (4)**

**Generated On: 26 Nov 2020 10:51:06**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '20/Nov/2020 15:43'	System	20 Nov 2020 15:43:24

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:51:06

**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)	20 Nov 2020 15:43:24