

US3292103 (Prod: Clinical Trials of Texas, Inc)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:55:50

All time stamps listed in this document are displayed in GMT

**US3292103**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 10:55:50**

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[Participant ID](#)

US3292103

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

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US3292103

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:55:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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 10:55:50

Date of Birth (MMM yyyy)	(b) (6) 1955
Age	65
Age Units	YEARS
Age (Derived)	65
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:50

Date of Informed Consent ( <i>dd MMM yyyy</i> )	8 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 10:55:50

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

**US3292103**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 26 Nov 2020 10:55:50**

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:50

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



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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:50

Condition	HARRINGTON ROD IMPLANT
Start date (dd MMM yyyy)	UN UNK 1974
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1974
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1974
Start Year (derived)	1974
Stop Month and Year (derived)	JAN 1974
Stop Year (derived)	1974

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:55:50

Condition	TOTAL HIP REPLACEMENT
Start date (dd MMM yyyy)	UN UNK 1999
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1999
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1999
Start Year (derived)	1999
Stop Month and Year (derived)	JAN 1999
Stop Year (derived)	1999

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:50

Condition	C-SECTION
Start date (dd MMM yyyy)	UN APR 1984
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 APR 1984
Stop date completely unknown	False
Start Month and Year (derived)	APR 1984
Start Year (derived)	1984
Stop Month and Year (derived)	APR 1984
Stop Year (derived)	1984

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:50

Condition	C-SECTION
Start date (dd MMM yyyy)	UN AUG 1988
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)	UN AUG 1988
Stop date completely unknown	False
Start Month and Year (derived)	AUG 1988
Start Year (derived)	1988
Stop Month and Year (derived)	AUG 1988
Stop Year (derived)	1988

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:50

Condition	BILATERAL DECREASED VISUAL ACUITY
Start date (dd MMM yyyy)	UN UNK 1963
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 1963
Start Year (derived)	1963
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:50

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

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:55:50

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:50

Condition	ESOPHAGEAL REFLUX (GERD)
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:50

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

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:50

Condition	CHRONIC GENERALIZED JOINT PAIN
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:55:50

Condition	BILATERAL HIP RHEUMATOID ARTHRITIS
Start date (dd MMM yyyy)	UN UNK 1967
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	JAN 1967
Start Year (derived)	1967
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:55:50

Condition	SCOLIOSIS
Start date (dd MMM yyyy)	UN UNK 1974
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1974
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1974
Start Year (derived)	1974
Stop Month and Year (derived)	JAN 1974
Stop Year (derived)	1974

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:55:50

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

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Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:55:50

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	08 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	16:05 (24 HR)
Vital Signs Date and Time (derived)	08 AUG 2020 16:05
Height ( <i>xxx.x</i> )	159.3 cm
Weight ( <i>xxx.x</i> )	62.9 kg
BMI ( <i>xxx.x</i> )	24.78672 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 10:55:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 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: Childbearing Potential

Generated On: 26 Nov 2020 10:55:50

Date of assessment ( <i>dd MMM yyyy</i> )	08 AUG 2020
Is the participant of childbearing potential?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If No, what is the reason?	Surgically sterile <input type="radio"/>
	Post-menopausal <input checked="" type="radio"/>
	Partner medically sterile <input type="radio"/>
	Not reached age of Menarche <input type="radio"/>
	Other <input type="radio"/>
If Partner medically sterile or Other, specify _____	
If Surgically sterile, date of surgery ( <i>dd MMM yyyy</i> ) _____	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation ( <i>dd MMM yyyy</i> )	UN UNK 2007
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:50

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** True

**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 10:55:50

<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)	False
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:55:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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 10:55:50

What was the date of randomization? (dd MMM yyyy) 08 AUG 2020

What was the participant's randomization number? 185367

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 26 Nov 2020 10:55:50**

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 10:55:50

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)	08 AUG 2020
Time of assessment (00:00-23:59)	16:05 (24 HR)
Vital Signs Date and Time (derived)	08 AUG 2020 16:05
Temperature (xxx.x)	037.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	078 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	012 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	159 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	081 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 10:55:50

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)	08 AUG 2020
Time of assessment (00:00-23:59)	18:55 (24 HR)
Vital Signs Date and Time (derived)	08 AUG 2020 18:55
Temperature (xxx.x)	037.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	084 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	014 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	157 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	084 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:50

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:50

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)	8 AUG 2020
What was the treatment time? (00:00-23:59)	18:22 (24 HR)
Treatment Date and Time (derived)	8 AUG 2020 18:22
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	08 AUG 2020
Collection time ( <i>00:00-23:59</i> )	16:30 (24 HR)
Collection date and time (derived)	08 AUG 2020 16:30

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:55:50

Collection date ( <i>dd MMM yyyy</i> )			08 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	16:25	08 AUG 2020 16:25
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:55:50

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 10:55:50

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 18:55

PC Open Date & Time

08 AUG 2020 18:42

PC Close Date & Time

08 AUG 2020 21:12

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:55:50

**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 97.3 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 08 AUG 2020 22:08

PC Open Date & Time 08 AUG 2020 22:07

PC Close Date & Time 09 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:55:50

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.2 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	09 AUG 2020 18:01
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59



US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:55:50

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 10 AUG 2020 18:28

PC Open Date & Time 10 AUG 2020 12:00

PC Close Date & Time 11 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:55:50

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.8 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 11 AUG 2020 16:57

PC Open Date & Time 11 AUG 2020 12:00

PC Close Date & Time 12 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:55:50

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.2 °F
Was any <b>MEDICATION TAKEN today for pain or fever?</b>	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	12 AUG 2020 17:33
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:55:50

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

13 AUG 2020 17:24

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:55:50

**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.

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.0 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	14 AUG 2020 16:51
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 26 Nov 2020 10:55:50

**TIMEPOINT**

DAY 8

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

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

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

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

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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

15 AUG 2020 15:58

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 26 Nov 2020 10:55:50

**TIMEPOINT**

DAY 9

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

16 AUG 2020 15:16

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 26 Nov 2020 10:55:50

**TIMEPOINT**

DAY 10

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

17 AUG 2020 14:18

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59



US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 26 Nov 2020 10:55:50

**TIMEPOINT**

DAY 11

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

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

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.

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.2 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	18 AUG 2020 16:07
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 26 Nov 2020 10:55:50

**TIMEPOINT**

DAY 12

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.2 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	19 AUG 2020 18:17
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 26 Nov 2020 10:55:50

**TIMEPOINT**

DAY 13

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.0 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	20 AUG 2020 15:24
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 26 Nov 2020 10:55:50

**TIMEPOINT**

DAY 14

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.2 °F
Was any <b>MEDICATION TAKEN today for pain or fever?</b>	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

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

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 26 Nov 2020 10:55:50

**TIMEPOINT**

DAY 15

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.0 °F
Was any <b>MEDICATION TAKEN today for pain or fever?</b>	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	22 AUG 2020 17:12
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(16)

Generated On: 26 Nov 2020 10:55:50

**TIMEPOINT**

DAY 16

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

23 AUG 2020 16:07

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(17)

Generated On: 26 Nov 2020 10:55:50

---

**TIMEPOINT**

DAY 17

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

24 AUG 2020 14:54

---

PC Open Date & Time

24 AUG 2020 12:00

---

PC Close Date & Time

25 AUG 2020 11:59

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US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:55:50

**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

08 AUG 2020 18:55

PC Open Date & Time

08 AUG 2020 18:42

PC Close Date & Time

08 AUG 2020 21:12



US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:55:50

**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

08 AUG 2020 22:09

PC Open Date & Time

08 AUG 2020 22:07

PC Close Date & Time

09 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:55:50

**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

09 AUG 2020 18:02

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:55:50

**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

10 AUG 2020 18:29

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:55:50

**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

11 AUG 2020 16:58

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:55:50

**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

12 AUG 2020 17:34

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:55:50

**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

13 AUG 2020 17:24

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:55:50

**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

14 AUG 2020 16:51

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:55:50

**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 ☐



US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:55:50

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

No ☒

Yes ☐

PC Time stamp	08 AUG 2020 18:56
PC Open Date & Time	08 AUG 2020 18:42
PC Close Date & Time	08 AUG 2020 21:12

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:55:50

**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 ☐

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:55:50

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

No ☒

Yes ☐

PC Time stamp	08 AUG 2020 22:10
PC Open Date & Time	08 AUG 2020 22:07
PC Close Date & Time	09 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:55:50

**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 ☒

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:55:50

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 18:03
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:55:50

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 ☒

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:55:50

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 18:30
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:55:50

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 ☒



US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:55:50

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 16:58
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:55:50

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 ☒

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:55:50

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 17:35
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:55:50

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 ☒

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:55:50

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 17:25
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:55:50

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 ☒

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:55:50

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 16:52
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 26 Nov 2020 10:55:50

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	15 AUG 2020 15:58
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59



US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 26 Nov 2020 10:55:50

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 AUG 2020 15:16
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 26 Nov 2020 10:55:50

<b>TIMEPOINT</b>	DAY 10
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 AUG 2020 14:18
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 26 Nov 2020 10:55:50

<b>TIMEPOINT</b>	DAY 11
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 AUG 2020 16:07
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 26 Nov 2020 10:55:50

<b>TIMEPOINT</b>	DAY 12
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 AUG 2020 18:17
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 26 Nov 2020 10:55:50

<b>TIMEPOINT</b>	DAY 13
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 AUG 2020 15:24
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 26 Nov 2020 10:55:50

<b>TIMEPOINT</b>	DAY 14
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 AUG 2020 23:59
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(15)

Generated On: 26 Nov 2020 10:55:50

<b>TIMEPOINT</b>	DAY 15
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 AUG 2020 17:12
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(16)

Generated On: 26 Nov 2020 10:55:50

<b>TIMEPOINT</b>	DAY 16
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 AUG 2020 16:07
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59



US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(17)

Generated On: 26 Nov 2020 10:55:50

<b>TIMEPOINT</b>	DAY 17
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 AUG 2020 14:54
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3292103

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:50

Was Contact Attempted?

Yes ☒

No ☐

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

17 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292103

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292103

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:50

Was Contact Attempted?

Yes ☒

No ☐

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

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292103

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3292103**

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

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:50**

Was Contact Attempted?

Yes ☒

No ☐

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

29 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292103

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292103

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 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



US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:50

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)	5 SEP 2020
Time of assessment (00:00-23:59)	12:33 (24 HR)
Vital Signs Date and Time (derived)	5 SEP 2020 12:33
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:50

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)	5 SEP 2020
Time of assessment (00:00-23:59)	13:51 (24 HR)
Vital Signs Date and Time (derived)	5 SEP 2020 13:51
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)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3292103

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 SEP 2020

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

US3292103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:50

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)	5 SEP 2020
What was the treatment time? (00:00-23:59)	13:21 (24 HR)
Treatment Date and Time (derived)	5 SEP 2020 13:21
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

US3292103

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	5 SEP 2020
Collection time ( <i>00:00-23:59</i> )	12:42 (24 HR)
Collection date and time (derived)	5 SEP 2020 12:42

US3292103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:55:50

Collection date ( <i>dd MMM yyyy</i> )			5 SEP 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:48	5 SEP 2020 12:48
Nasopharyngeal Swab 2	No		

US3292103

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:55:50

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 13:54

PC Open Date & Time

05 SEP 2020 13:41

PC Close Date & Time

05 SEP 2020 16:11



US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:55:50

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	05 SEP 2020 19:33
PC Open Date & Time	05 SEP 2020 17:06
PC Close Date & Time	06 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:55:50

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

06 SEP 2020 18:31

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:55:50

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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

98.2 °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

07 SEP 2020 17:03

---

PC Open Date & Time

07 SEP 2020 12:00

---

PC Close Date & Time

08 SEP 2020 11:59

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US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:55:50

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 19:14

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:55:50

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.0 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

09 SEP 2020 17:14

---

PC Open Date & Time

09 SEP 2020 12:00

---

PC Close Date & Time

10 SEP 2020 11:59

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US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:55:50

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 18:33

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:55:50

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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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 17:32

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:55:50

**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

05 SEP 2020 13:54

PC Open Date & Time

05 SEP 2020 13:41

PC Close Date & Time

05 SEP 2020 16:11



US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:55:50

**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 19:34

PC Open Date & Time

05 SEP 2020 17:06

PC Close Date & Time

06 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:55:50

**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

06 SEP 2020 18:32

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:55:50

**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

07 SEP 2020 17:04

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:55:50

**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 19:14

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:55:50

**TIMEPOINT**

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 17:15

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:55:50

**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 18:34

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:55:50

**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

11 SEP 2020 17:32

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:55:50

**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 ☐



US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:55:50

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

No ☒

Yes ☐

PC Time stamp	05 SEP 2020 13:55
PC Open Date & Time	05 SEP 2020 13:41
PC Close Date & Time	05 SEP 2020 16:11

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:55:50

**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 ☐

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:55:50

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

No ☒

Yes ☐

PC Time stamp	05 SEP 2020 19:34
PC Open Date & Time	05 SEP 2020 17:06
PC Close Date & Time	06 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:55:50

**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 ☒

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:55:50

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 18:32
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:55:50

**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 ☒

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:55:50

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 17:04
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:55:50

**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 ☒



US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:55:50

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 19:14
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:55:50

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 ☒

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:55:50

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 17:15
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:55:50

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 ☒

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:55:50

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 18:34
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:55:50

**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 ☒

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:55:50

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 17:33
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 26 Nov 2020 10:55:50

**TIMEPOINT**

DAY 8

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 ☐

PC Time Stamp 12 SEP 2020 12:21

PC Open Date & Time 12 SEP 2020 12:00

PC Close Date & Time 13 SEP 2020 11:59



US3292103

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 26 Nov 2020 10:55:50

<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	12 SEP 2020 12:21
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3292103

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:50

Was Contact Attempted?

Yes ☒

No ☐

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

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292103

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292103

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:50

Was Contact Attempted?

Yes ☒

No ☐

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

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292103

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292103

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:50

Was Contact Attempted?

Yes ☒

No ☐

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

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292103

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292103

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 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



US3292103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	6 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	10:27 (24 HR)
Vital Signs Date and Time (derived)	6 OCT 2020 10:27
Temperature ( <i>xxx.x</i> )	36.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	70 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	12 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> )	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3292103

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:50

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3292103

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	6 OCT 2020
Collection time ( <i>00:00-23:59</i> )	10:40 (24 HR)
Collection date and time (derived)	6 OCT 2020 10:40

US3292103

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 OCT 2020 11:49:07

Patient Cloud Open Date & Time

08 OCT 2020 00:01

Patient Cloud Close Date & Time

12 OCT 2020 23:59

US3292103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 OCT 2020 14:00:21

Patient Cloud Open Date & Time

15 OCT 2020 00:01

Patient Cloud Close Date & Time

19 OCT 2020 23:59

US3292103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 OCT 2020 13:37:05

Patient Cloud Open Date & Time

22 OCT 2020 00:01

Patient Cloud Close Date & Time

26 OCT 2020 23:59

US3292103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

**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

06 NOV 2020 12:12:36

Patient Cloud Open Date & Time

05 NOV 2020 00:01

Patient Cloud Close Date & Time

09 NOV 2020 23:59



US3292103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 NOV 2020 17:40:52
Patient Cloud Open Date & Time	12 NOV 2020 00:01
Patient Cloud Close Date & Time	16 NOV 2020 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Close Date & Time](#)

09 OCT 2020 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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="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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Close Date & Time](#)

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23 OCT 2020 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

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26 OCT 2020 00:01

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[Patient Cloud Close Date & Time](#)

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30 OCT 2020 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

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02 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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06 NOV 2020 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Close Date & Time](#)

13 NOV 2020 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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="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	19 NOV 2020 17:36:24
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 NOV 2020 10:32:55

Patient Cloud Open Date & Time

23 NOV 2020 00:01

Patient Cloud Close Date & Time

27 NOV 2020 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

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30 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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04 DEC 2020 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Close Date & Time](#)

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11 DEC 2020 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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="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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

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14 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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18 DEC 2020 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

**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 ☐

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this 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>	21 DEC 2020 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	25 DEC 2020 23:59
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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	28 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	01 JAN 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

04 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 JAN 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Close Date & Time](#)

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15 JAN 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

18 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 JAN 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

25 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

29 JAN 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

**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 ☐

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

08 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 FEB 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 FEB 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 FEB 2021 23:59
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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Close Date & Time](#)

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05 MAR 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Close Date & Time](#)

12 MAR 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

**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 ☐

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 MAR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 MAR 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Close Date & Time](#)

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02 APR 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Close Date & Time](#)

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09 APR 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

19 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 APR 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

**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 ☐

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Close Date & Time](#)

07 MAY 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

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17 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 MAY 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

31 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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 ☐

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Close Date & Time](#)

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02 JUL 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

**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 ☐

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

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26 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 JUL 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Close Date & Time](#)

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06 AUG 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

**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 ☐



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

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09 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 AUG 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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°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 ☐

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Close Date & Time](#)

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20 AUG 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	23 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	27 AUG 2021 23:59
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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

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30 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 SEP 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

**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 ☐



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 SEP 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

13 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

**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 ☐

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Close Date & Time](#)

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01 OCT 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

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04 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 OCT 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

**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 ☐

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Close Date & Time](#)

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15 OCT 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this 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 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 OCT 2021 23:59
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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

**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 ☐



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Close Date & Time](#)

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05 NOV 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

08 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 NOV 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Close Date & Time](#)

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26 NOV 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 DEC 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

06 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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 ☐



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

03 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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 ☐

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

10 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Close Date & Time](#)

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21 JAN 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

**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 ☐



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

31 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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 ☐

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Close Date & Time](#)

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11 FEB 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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 ☐

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

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14 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 FEB 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

**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 ☐



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

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21 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 FEB 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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°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 ☐

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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 ☐

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

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07 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAR 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

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14 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAR 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Close Date & Time](#)

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01 APR 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

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04 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 APR 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 APR 2022 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Close Date & Time](#)

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06 MAY 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this 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>	09 MAY 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	13 MAY 2022 23:59
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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

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16 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAY 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

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23 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAY 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

30 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

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13 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 JUN 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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="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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

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20 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 JUN 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

04 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 JUL 2022 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

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01 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 AUG 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

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08 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 AUG 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2022 23:59
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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

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22 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 AUG 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

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29 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 SEP 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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"/>



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

12 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	19 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 SEP 2022 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

**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 ☐

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

26 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

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[Patient Cloud Open Date & Time](#)

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03 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 OCT 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:50

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="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"/>

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 OCT 2022 23:59

US3292103

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:50

Was Contact Attempted?

Yes ☒

No ☐

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

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292103

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3292103**

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

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:50**

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*

**US3292103**

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

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:50**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3292103**

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

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 10:55:50**

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"/>



**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3292103

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:55:50

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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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US3292103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:50

AEID	USA-US072-2020-MRNA-1273-P30 1000013
Adverse event	SUBDURAL HEMATOMA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	14 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	15 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	17 NOV 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	3

v6.020 DTW (1102)

370 of 2179

US3292103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:50

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	True
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	

US3292103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:50

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PATIENT CALLED STAFF ON  
20NOV2020 TO REPORT THAT  
SHE HAD BEEN HOSPITALIZED  
FOR THREE DAYS DUE TO A  
SUBDURAL HEMATOMA  
SUFFERED AFTER A FALL.  
PATIENT DOES HAVE A  
MEDICAL HISTORY OF ROD  
IMPLANT DUE TO SCOLIOSIS  
AND A TOTAL HIP  
REPLACEMENT DUE TO  
RHEUMATOID ARTHRITIS,  
WHICH SHE CLAIMS,  
CONTRIBUTED TO HER FALL.  
PATIENT STATES SHE WAS  
TESTED FOR COVID-19 AND  
TESTS CAME BACK NEGATIVE.  
INTAKE AND DISCHARGE CT  
SCANS COMPLETED AND  
KEPPRA WAS PRESCRIBED  
WHILE INPATIENT TO PREVENT  
SEIZURES. MEDICAL RECORDS  
WILL BE REQUESTED ASAP.

---

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)	1

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US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:55:50

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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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US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:50

Name of Medication	TYLENOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	GENERALIZED JOINT PAIN
Dose per administration	325
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:50

	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 2000	
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"/>



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:50

Name of Medication	MAGNESIUM CITRATE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	GENERAL HEALTH
Dose per administration	250
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"/>

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:50

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:50

Name of Medication	ALLEGRA
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SEASONAL ALLERGIES
Dose per administration	180
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input 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"/>

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:50

	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 2019
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	<input type="text"/>	
Interval Dosage Unit Number (derived)	<input type="text"/>	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:50

Name of Medication	FISH OIL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	GENERAL HEALTH
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"/>

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:50

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:50

Name of Medication	CENTRUM SILVER
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	GENERAL HEALTH
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input checked="" 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"/>

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:50

Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input checked="" type="radio"/>



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:50

Name of Medication	VITAMIN K
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	GENERAL HEALTH
Dose per administration	100
Dose unit	mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input 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"/>

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:50

Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input checked="" type="radio"/>

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:50

Name of Medication	VITAMIN D3
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	GENERAL HEALTH
Dose per administration	1000
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input checked="" 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"/>

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:50

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:50

Name of Medication	CALCIUM
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	GENERAL HEALTH
Dose per administration	600
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:50

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:50

Name of Medication	VITAMIN B
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	GENERAL HEALTH
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:50

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:50

Name of Medication	METOPROLOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERTENSION
Dose per administration	25
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:50

	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 2005	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:50

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:50

	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 2005	
Start date completely unknown	False	
Ongoing?	Yes <input checked="" type="radio"/>	No <input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes <input type="radio"/>	No <input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	803 <input type="radio"/>
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:50

Name of Medication	ATORVASTATIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERCHOLESTEROLEMIA
Dose per administration	40
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:50

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:50

Name of Medication	LOSTARTAN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERTENSION
Dose per administration	100
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:50

	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 2005	
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"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:50

Name of Medication	ARMOUR THYROID
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	HYPOTHYROID
Dose per administration	60
Dose unit	mg <input type="checkbox"/> ug <input checked="" type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:50

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:55:50

Name of Medication	PROGESTERONE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	LOW PROGESTERONE
Dose per administration	200
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"/>

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:55:50

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:50

Name of Medication	NEXIUM
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	GERD
Dose per administration	40
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:50

	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 2000
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"/>

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:55:50

Name of Medication	KEPPRA
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	SEIZURE PREVENTION FOLLOWING SUBDURAL HEMATOMA
Dose per administration	750
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"/>

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:55:50

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 NOV 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"/>



US3292103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:55:50

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3292103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 10:55:50

Procedure/Surgery date ( <i>dd MMM yyyy</i> )	Procedure/Surgery	Indication	If indication is Other, specify
15 NOV 2020	HEAD CT	Adverse Event	
17 NOV 2020	HEAD CT	Adverse Event	

US3292103

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:55:50

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

US3292103

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:55:50

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 ☐

US3292103

Folder: SAE USA-US072-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:50

SAEID	USA-US072-2020-MRNA-1273-P301000013
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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3292103

Folder: SAE USA-US072-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:55:50

SAEID	USA-US072-2020-MRNA-1273-P301000013
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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	23/NOV/2020 18:38
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3292103 (Prod: Clinical Trials of Texas, Inc)

**US3292103**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 10:55:50**

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3292103'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	08 Aug 2020 22:15:31



**US3292103**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:55:50**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 15:55:06

**US3292103**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered '08 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	08 Aug 2020 22:15:32

US3292103

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Aug 2020 15:55:06

**US3292103**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:55:50**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	11 Aug 2020 15:55:06

**US3292103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered (b) (6) 1955'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	08 Aug 2020 22:15:33

**US3292103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:55:50**

[Age](#)

Audit	User	Time (GMT)
User entered '65'	(b) (4), (b) (6)	11 Aug 2020 15:55:29

**US3292103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:55:50**

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	11 Aug 2020 15:55:29

**US3292103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:55:50**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '65'	System	08 Aug 2020 23:38:10



**US3292103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:55:50**

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	(b) (4), (b) (6)	11 Aug 2020 15:55:29

**US3292103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:55:50**

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	11 Aug 2020 15:55:29

**US3292103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:55:50**

[White](#)

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	11 Aug 2020 15:55:29

**US3292103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:55:50**

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 15:55:29

**US3292103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:55:50**

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 15:55:29

US3292103

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:50

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 15:55:29

**US3292103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:55:50**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 15:55:29

**US3292103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:55:50**

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 15:55:29



**US3292103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:55:50**

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 15:55:29

**US3292103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:55:50**

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 15:55:29

**US3292103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:55:50**

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 15:55:29

**US3292103**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:55:50**

**Date of Informed Consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Aug 2020'	Darlington Akahara (b) (4)	08 Aug 2020 23:38:10

**US3292103**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	08 Aug 2020 23:38:10

**US3292103**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered '2020'	System	08 Aug 2020 23:38:10

**US3292103**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:55:50**

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	Darlington Akahara (b) (4)	08 Aug 2020 23:38:10

**US3292103**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Darlington Akahara (b) (4)	08 Aug 2020 23:38:10



**US3292103**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	Darlington Akahara (b) (4)	08 Aug 2020 23:38:10

**US3292103**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:55:50**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Darlington Akahara (b) (4)	08 Aug 2020 23:38:10

**US3292103**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:55:50**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Darlington Akahara (b) (4)	08 Aug 2020 23:38:10

**US3292103**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:55:50**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	08 Aug 2020 22:15:32

**US3292103**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:55:50**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 23:38:24

**US3292103**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Darlington Akahara (b) (4)	08 Aug 2020 23:38:24

**US3292103**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 26 Nov 2020 10:55:50**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 15:55:34

US3292103

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:50

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 07:16:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 07:16:20
Data point term sent to Coder	System	11 Aug 2020 15:57:21
User entered 'environmental cedar allergy'	(b) (4), (b) (6) (b) (4) (b) (4)	11 Aug 2020 15:57:03



**US3292103**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'UN UNK 1990' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 16:22:39
User entered 'un UNK 1996'	(b) (4), (b) (6)	11 Aug 2020 15:57:03

**US3292103**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 15:57:03

**US3292103**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 15:57:03

**US3292103**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 15:57:03

**US3292103**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 15:57:03

**US3292103**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	11 Aug 2020 16:22:39
User entered 'Jan 1996'	System	11 Aug 2020 15:57:03

**US3292103**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered '1990'	System	11 Aug 2020 16:22:39
User entered '1996'	System	11 Aug 2020 15:57:03

**US3292103**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 15:57:03



**US3292103**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 15:57:03

US3292103

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:50

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Medical device implantation, LLT: Insertion of surgical hardware - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 09:42:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 09:42:12
Data point term sent to Coder	System	11 Aug 2020 15:58:25
User entered 'Harrington rod implant'	(b) (4), (b) (6) (b) (4) (b) (4)	11 Aug 2020 15:57:49

**US3292103**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'un UNK 1974'	(b) (4), (b) (6)	11 Aug 2020 15:57:49

**US3292103**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 15:57:49

**US3292103**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:55:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 15:57:49

**US3292103**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'un UNK 1974'	(b) (4), (b) (6)	11 Aug 2020 15:57:49

**US3292103**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:55:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 15:57:49

**US3292103**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'Jan 1974'	System	11 Aug 2020 15:57:49



**US3292103**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered '1974'	System	11 Aug 2020 15:57:49

**US3292103**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'Jan 1974'	System	11 Aug 2020 15:57:49

**US3292103**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered '1974'	System	11 Aug 2020 15:57:49

US3292103

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:55:50

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the location where the TOTAL HIP REPLACEMENT was performed (e.g. right, left or both hips). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 20:56:05
Query 'Per DM CLR: Please specify the location where the TOTAL HIP REPLACEMENT was performed (e.g. right, left or both hips). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'total hip replacement, correct as entered, both hips.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 18:12:08
User opened query 'Per DM CLR: Please specify the location where the TOTAL HIP REPLACEMENT was performed (e.g. right, left or both hips). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 19:47:29
User coded data point as SOC: Surgical and medical procedures, HLG: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Total hip replacement - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 15:59:14
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 15:59:14
Data point term sent to Coder	System	11 Aug 2020 15:58:26
User entered 'Total hip replacement'	(b) (4), (b) (6)	11 Aug 2020 15:58:10

**US3292103**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'un UNK 1999'	(b) (4), (b) (6)	11 Aug 2020 15:58:10

**US3292103**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 15:58:10

**US3292103**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:55:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 15:58:10

**US3292103**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'un UNK 1999'	(b) (4), (b) (6)	11 Aug 2020 15:58:10



**US3292103**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:55:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 15:58:10

**US3292103**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'Jan 1999'	System	11 Aug 2020 15:58:10

**US3292103**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered '1999'	System	11 Aug 2020 15:58:10

**US3292103**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'Jan 1999'	System	11 Aug 2020 15:58:10

**US3292103**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered '1999'	System	11 Aug 2020 15:58:10

US3292103

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:50

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: C-section - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:00:14
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 16:00:14
Data point term sent to Coder	System	11 Aug 2020 15:59:27
User entered 'C-Section'	(b) (4), (b) (6) (b) (4) (b) (4)	11 Aug 2020 15:58:35

**US3292103**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'un Apr 1984'	(b) (4), (b) (6)	11 Aug 2020 15:58:35

**US3292103**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 15:58:35



**US3292103**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:55:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 15:58:35

**US3292103**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'un Apr 1984'	(b) (4), (b) (6)	11 Aug 2020 15:58:35

**US3292103**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:55:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 15:58:35

**US3292103**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'Apr 1984'	System	11 Aug 2020 15:58:35

**US3292103**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered '1984'	System	11 Aug 2020 15:58:35

**US3292103**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'Apr 1984'	System	11 Aug 2020 15:58:35

**US3292103**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered '1984'	System	11 Aug 2020 15:58:35

US3292103

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:50

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: C-section - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:00:16
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 16:00:16
Data point term sent to Coder	System	11 Aug 2020 15:59:28
User entered 'C-Section'	(b) (4), (b) (6)   	11 Aug 2020 15:59:02



**US3292103**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'un Aug 1988'	(b) (4), (b) (6)	11 Aug 2020 15:59:02

**US3292103**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 15:59:02

**US3292103**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:55:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 15:59:02

**US3292103**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'un Aug 1988'	(b) (4), (b) (6)	11 Aug 2020 15:59:02

**US3292103**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:55:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 15:59:02

**US3292103**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'Aug 1988'	System	11 Aug 2020 15:59:02

**US3292103**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered '1988'	System	11 Aug 2020 15:59:02

**US3292103**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'Aug 1988'	System	11 Aug 2020 15:59:02



**US3292103**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered '1988'	System	11 Aug 2020 15:59:02

US3292103

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:50

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the location where the DECREASED VISUAL ACUITY is affecting (e.g. right, left or both eyes). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 09:50:10
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual impairment and blindness (excl colour blindness), PT: Visual acuity reduced, LLT: Visual acuity decreased - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 18:13:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 18:13:53
Data point term sent to Coder	System	21 Sep 2020 18:12:52
Query 'Per DM CLR: Please specify the location where the DECREASED VISUAL ACUITY is affecting (e.g. right, left or both eyes). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 18:12:33
Coding entries removed.	(b) (4), (b) (6)	21 Sep 2020 18:12:27
User entered 'Bilateral DECREASED VISUAL ACUITY' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 18:12:27
User opened query 'Per DM CLR: Please specify the location where the DECREASED VISUAL ACUITY is affecting (e.g. right, left or both eyes). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 19:38:59
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual impairment and blindness (excl colour blindness), PT: Visual acuity reduced, LLT: Visual acuity decreased - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:01:20
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 16:01:20

**US3292103**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:55:50**

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	11 Aug 2020 16:00:29
User entered 'Decreased visual acuity'	(b) (4), (b) (6)	11 Aug 2020 15:59:29

**US3292103**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'un UNK 1963'	(b) (4), (b) (6)	11 Aug 2020 15:59:29

**US3292103**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 15:59:29

US3292103

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 15:59:29

**US3292103**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 15:59:29

**US3292103**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:55:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 15:59:29



**US3292103**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'Jan 1963'	System	11 Aug 2020 15:59:29

**US3292103**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered '1963'	System	11 Aug 2020 15:59:29

**US3292103**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 15:59:29

**US3292103**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 15:59:29

US3292103

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:50

[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 16:01:20
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 16:01:20
Data point term sent to Coder	System	11 Aug 2020 16:00:31
User entered 'Hypercholersterolemia'	(b) (4), (b) (6) (b) (4) (b) (4)	11 Aug 2020 15:59:50

**US3292103**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	(b) (4), (b) (6)	11 Aug 2020 15:59:50

**US3292103**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 15:59:50

US3292103

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 15:59:50



**US3292103**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 15:59:50

**US3292103**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:55:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 15:59:50

**US3292103**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	11 Aug 2020 15:59:50

**US3292103**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered '2015'	System	11 Aug 2020 15:59:50

**US3292103**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 15:59:50

**US3292103**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 15:59:50

US3292103

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:55:50

[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 16:01:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:01:42
Data point term sent to Coder	System	11 Aug 2020 16:00:31
User entered 'Hypertension'	(b) (4), (b) (6) (b) (4) (b) (4)	11 Aug 2020 16:00:10

**US3292103**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'un UNK 2005'	(b) (4), (b) (6)	11 Aug 2020 16:00:10



**US3292103**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:00:10

**US3292103**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:55:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:00:10

**US3292103**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:00:10

**US3292103**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:55:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:00:10

**US3292103**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	11 Aug 2020 16:00:10

**US3292103**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered '2005'	System	11 Aug 2020 16:00:10

**US3292103**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 16:00:10

**US3292103**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 16:00:10



US3292103

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:50

[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: Esophageal reflux - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 13:31:22
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 13:31:22
Data point term sent to Coder	System	11 Aug 2020 16:01:32
User entered 'esophageal reflux (GERD)'	(b) (4), (b) (6) (b) (4) (b) (4)	11 Aug 2020 16:00:34

**US3292103**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	(b) (4), (b) (6)	11 Aug 2020 16:00:34

**US3292103**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:00:34

**US3292103**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:55:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:00:34

**US3292103**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:00:34

**US3292103**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:55:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:00:34

**US3292103**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	11 Aug 2020 16:00:34

**US3292103**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered '2000'	System	11 Aug 2020 16:00:34



**US3292103**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 16:00:34

**US3292103**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 16:00:34

US3292103

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:50

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:02:09
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 16:02:09
Data point term sent to Coder	System	11 Aug 2020 16:01:33
User entered 'Hypothyroid'	(b) (4), (b) (6)   	11 Aug 2020 16:00:49

**US3292103**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	(b) (4), (b) (6)	11 Aug 2020 16:00:49

**US3292103**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:00:49

US3292103

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:00:49

**US3292103**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:00:49

**US3292103**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:55:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:00:49



**US3292103**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	11 Aug 2020 16:00:49

**US3292103**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered '2015'	System	11 Aug 2020 16:00:49

**US3292103**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 16:00:49

**US3292103**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 16:00:49

US3292103

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:50

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the condition to include the location of Joint Pain (arms, Legs, Generalized, etc.). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 09:50:44
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Generalized joint pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 18:37:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 18:37:09
Data point term sent to Coder	System	24 Sep 2020 16:17:49
Query 'Per DM CLR: Please update the condition to include the location of Joint Pain (arms, Legs, Generalized, etc.). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4) (b) (4)	24 Sep 2020 16:16:53
Coding entries removed.	Victoria Hernandez (b) (4) (b) (4)	24 Sep 2020 16:16:48
User entered 'CHRONIC GENERALIZED JOINT PAIN' reason for change: Data Entry Error	Victoria Hernandez (b) (4) (b) (4)	24 Sep 2020 16:16:48
User opened query 'Per DM CLR: Please update the condition to include the location of Joint Pain (arms, Legs, Generalized, etc.). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 19:39:49
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 15:43:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 15:43:37
Data point term sent to Coder	System	11 Aug 2020 16:01:33
User entered 'chronic joint pain'	(b) (4), (b) (6)	11 Aug 2020 16:01:07

**US3292103**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	(b) (4), (b) (6)	11 Aug 2020 16:01:07

**US3292103**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:01:07

**US3292103**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:55:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:01:07



**US3292103**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:01:07

**US3292103**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:55:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:01:07

**US3292103**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	11 Aug 2020 16:01:07

**US3292103**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered '2000'	System	11 Aug 2020 16:01:07

**US3292103**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 16:01:07

**US3292103**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 16:01:07

US3292103

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:55:50

Condition

Audit	User	Time (GMT)
Query 'Per CDM: Please confirm if participant is treating condition with medication. If yes, update the Concomitant medication eCRF or provide an explanation for no medical treatment.' answered with 'patient is not prescribed to take medication for this condition' (Site from DM).	Kevin Martinez (b) (4)	04 Nov 2020 22:43:17
User opened query 'Per CDM: Please confirm if participant is treating condition with medication. If yes, update the Concomitant medication eCRF or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 14:29:30
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 14:29:30
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Rheumatoid arthropathies, PT: Rheumatoid arthritis, LLT: Rheumatoid arthritis - version MedDRA\23.0.	Coder Import (b) (4)	24 Sep 2020 21:51:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Sep 2020 21:51:43
Data point term sent to Coder	System	24 Sep 2020 16:19:55
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	24 Sep 2020 16:19:30
Coding entries removed.	Victoria Hernandez (b) (4)	24 Sep 2020 16:19:25
User entered 'BILATERAL HIP RHEUMATOID ARTHRITIS' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	24 Sep 2020 16:19:25
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 19:41:27

US3292103

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:55:50

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Rheumatoid arthropathies, PT: Rheumatoid arthritis, LLT: Rheumatoid arthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:02:10
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 16:02:10
Data point term sent to Coder	System	11 Aug 2020 16:01:33
User entered 'rheumatoid arthritis'	(b) (4), (b) (6) (b) (4) (b) (4)	11 Aug 2020 16:01:33



**US3292103**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'un UNK 1967'	(b) (4), (b) (6)	11 Aug 2020 16:01:33

**US3292103**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:01:33

**US3292103**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:55:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:01:33

US3292103

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
Query 'Per CDM: Response noted however it appears updates are incomplete. Since, stop date has been removed, please confirm if this condition is Ongoing and if yes, update appropriately.' canceled (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 22:26:13
User opened query 'Per CDM: Response noted however it appears updates are incomplete. Since, stop date has been removed, please confirm if this condition is Ongoing and if yes, update appropriately.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 14:16:36
User closed query 'Per DM CLR: Please review the stop date of this Chronic MH condition, as this condition is not expected to resolve. Please review and update stop date if appropriate or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 14:16:36
Query 'Per DM CLR: Please review the stop date of this Chronic MH condition, as this condition is not expected to resolve. Please review and update stop date if appropriate or provide explanation. ' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	24 Sep 2020 16:19:35
User entered empty; reason for change Data Entry Error	Victoria Hernandez (b) (4)	24 Sep 2020 16:19:25
User opened query 'Per DM CLR: Please review the stop date of this Chronic MH condition, as this condition is not expected to resolve. Please review and update stop date if appropriate or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 19:41:46
User entered 'un UNK 1999'	(b) (4), (b) (6)	11 Aug 2020 16:01:33

**US3292103**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:55:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	24 Sep 2020 16:19:25
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 16:01:33

**US3292103**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'Jan 1967'	System	11 Aug 2020 16:01:33

**US3292103**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered '1967'	System	11 Aug 2020 16:01:33

**US3292103**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 16:19:25
User entered 'Jan 1999'	System	11 Aug 2020 16:01:33



**US3292103**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 16:19:25
User entered '1999'	System	11 Aug 2020 16:01:33

US3292103

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:55:50

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Scoliosis, LLT: Scoliosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:03:11
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 16:03:11
Data point term sent to Coder	System	11 Aug 2020 16:02:34
User entered 'scoliosis'	(b) (4), (b) (6)   	11 Aug 2020 16:02:05

**US3292103**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'un UNK 1974'	(b) (4), (b) (6)	11 Aug 2020 16:02:05

**US3292103**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:02:05

**US3292103**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:55:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:02:05

**US3292103**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'un UNK 1974'	(b) (4), (b) (6)	11 Aug 2020 16:02:05

**US3292103**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:55:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:02:05

**US3292103**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'Jan 1974'	System	11 Aug 2020 16:02:05



**US3292103**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered '1974'	System	11 Aug 2020 16:02:05

**US3292103**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'Jan 1974'	System	11 Aug 2020 16:02:05

**US3292103**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered '1974'	System	11 Aug 2020 16:02:05

US3292103

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:55:50

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Endocrine investigations (incl sex hormones), HLT: Reproductive hormone analyses, PT: Progesterone decreased, LLT: Progesterone decreased - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Aug 2020 10:45:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Aug 2020 10:45:09
Data point term sent to Coder	System	11 Aug 2020 16:02:35
User entered 'low progesterone'	(b) (4), (b) (6) (b) (4) (b) (4)	11 Aug 2020 16:02:19

**US3292103**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	(b) (4), (b) (6)	11 Aug 2020 16:02:19

**US3292103**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:02:19

US3292103

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:55:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:02:19

**US3292103**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:02:19



**US3292103**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:55:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:02:19

**US3292103**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	11 Aug 2020 16:02:19

**US3292103**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered '2015'	System	11 Aug 2020 16:02:19

**US3292103**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 16:02:19

**US3292103**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 16:02:19

US3292103

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:55:50

[Condition](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review response to Is the Event/Condition Ongoing? = NO. As this condition's stop date is unexpected, please verify status of this condition and consider updating response to Is the Event/Condition Ongoing, as applicable. Also, Please note, Start date of MH = UN UNK 2000. However, Post-menopausal date recorded in Childbearing ecf is UN UNK 2007. Review and reconcile dates as appropriate. Ensure all details are recorded in the CB eCRF for appropriate match' answered with 'update' (Site from DM).	Dawn Killian (b) (4)	20 Oct 2020 19:14:25
User opened query 'Per DM CLR: Please review response to Is the Event/Condition Ongoing? = NO. As this condition's stop date is unexpected, please verify status of this condition and consider updating response to Is the Event/Condition Ongoing, as applicable. Also, Please note, Start date of MH = UN UNK 2000. However, Post-menopausal date recorded in Childbearing ecf is UN UNK 2007. Review and reconcile dates as appropriate. Ensure all details are recorded in the CB eCRF for appropriate match' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 03:03:20
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\23.0.	Coder Import (b) (4)	22 Sep 2020 20:59:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	22 Sep 2020 20:59:46
Data point term sent to Coder	System	22 Sep 2020 20:58:33
User entered 'POST MENOPAUSAL'	Victoria Hernandez (b) (4)	22 Sep 2020 20:58:09
	(b) (4)	

**US3292103**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'UN UNK 2000'	Victoria Hernandez (b) (4)	22 Sep 2020 20:58:09
	(b) (4)	

**US3292103**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Victoria Hernandez (b) (4)	22 Sep 2020 20:58:09
	(b) (4)	



US3292103

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:55:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Dawn Killian (b) (4)	20 Oct 2020 19:14:21
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 20:58:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 20:58:25
User entered 'No (N)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	22 Sep 2020 20:58:25
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 20:58:09
User entered empty.	Victoria Hernandez (b) (4)	22 Sep 2020 20:58:09

**US3292103**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	Victoria Hernandez (b) (4)	22 Sep 2020 20:58:09
	(b) (4)	

**US3292103**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:55:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0' reason for change: Data Entry Error	Dawn Killian (b) (4)	20 Oct 2020 19:14:21
	(b) (4)	
User entered '1'	Victoria Hernandez (b) (4)	22 Sep 2020 20:58:09
	(b) (4)	

**US3292103**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	22 Sep 2020 20:58:09

**US3292103**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered '2000'	System	22 Sep 2020 20:58:09

**US3292103**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:58:09

**US3292103**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:58:09

US3292103

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:03:07



**US3292103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:50**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 16:03:07

US3292103

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:50

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	24 Aug 2020 15:10:55
User entered '16:05' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 17:30:12
Query 'Data is required. Please provide.' answered with 'combined visit' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 16:03:13
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 16:03:07
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:03:07

**US3292103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:50**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 16:05'	System	14 Aug 2020 17:30:12
User entered empty.	System	11 Aug 2020 16:03:07

US3292103

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:50

Height (xxx.x)

Audit	User	Time (GMT)
User entered '159.3' cm	(b) (4), (b) (6)	11 Aug 2020 16:03:07
DataPoint set to visible.	System	08 Aug 2020 23:38:24

US3292103

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:50

Weight (xxx.x)

Audit	User	Time (GMT)
User entered '62.9' kg	(b) (4), (b) (6)	11 Aug 2020 16:03:07
DataPoint set to visible.	System	08 Aug 2020 23:38:24

**US3292103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:50**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered '24.78672'	System	16 Sep 2020 23:49:13
User entered '24.8'	System	11 Aug 2020 16:03:07
DataPoint set to visible.	System	08 Aug 2020 23:38:24

**US3292103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:50**

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	11 Aug 2020 16:03:07
DataPoint set to visible.	System	08 Aug 2020 23:38:24

US3292103

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:50

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	24 Aug 2020 15:10:59
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:43:26
Query 'Data is required. Please provide.' answered with 'combined visit' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 16:03:16
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 16:03:07
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:03:07



US3292103

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:50

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	24 Aug 2020 17:09:27
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 01:25:06
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:43:26
Query 'Data is required. Please provide.' answered with 'combined visit' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 16:03:19
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 16:03:07
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:03:07

**US3292103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:50**

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 01:25:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:43:26
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:03:07

US3292103

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	24 Aug 2020 15:11:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:43:26
Query 'Data is required. Please provide.' answered with 'combined visit' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 16:03:21
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 16:03:07
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:03:07

**US3292103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:50**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Aug 2020 19:43:26
User entered empty.	System	11 Aug 2020 16:03:07

US3292103

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	24 Aug 2020 15:11:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:43:26
Query 'Data is required. Please provide.' answered with 'combined visit' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 16:03:22
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 16:03:07
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:03:07

**US3292103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Aug 2020 19:43:26
User entered empty.	System	11 Aug 2020 16:03:07

US3292103

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:50

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	24 Aug 2020 15:11:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:43:26
Query 'Data is required. Please provide.' answered with 'combined visit' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 16:03:26
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 16:03:07
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:03:07

**US3292103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Aug 2020 19:43:26
User entered empty.	System	11 Aug 2020 16:03:07



US3292103

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:50

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	24 Aug 2020 15:11:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:43:26
Query 'Data is required. Please provide.' answered with 'combined visit' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 16:03:28
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 16:03:07
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:03:07

**US3292103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Aug 2020 19:43:26
User entered empty.	System	11 Aug 2020 16:03:07

**US3292103**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 10:55:50**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 01:25:26
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:03:32

US3292103

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:50

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 09:11:59
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		05 Sep 2020 19:14:02
User entered '8 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 01:25:26
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:03:32

**US3292103**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 10:55:50**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 16:03:58

US3292103

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:55:50

Is the participant of childbearing potential?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:03:58

US3292103

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:55:50

If No, what is the reason?

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 16:33:03
Query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	22 Sep 2020 20:58:51
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 04:47:17
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	11 Aug 2020 16:03:58

**US3292103**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 10:55:50**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:03:58



**US3292103**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 10:55:50**

**If Surgically sterile, date of surgery (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:03:58

**US3292103**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 10:55:50**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:03:58

US3292103

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:55:50

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered 'un UNK 2007'	(b) (4), (b) (6)	11 Aug 2020 16:03:58

**US3292103**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 10:55:50**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:03:58

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:50

**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 16:04:23

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:50

**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 16:04:23

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:50

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:04:23

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:50

**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 16:04:23



US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:50

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 16:04:23

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:50

**Transportation and delivery services** (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:04:23

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:50

**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 16:04:23

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:50

**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 16:04:23

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:50

[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 16:04:23

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:50

**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 16:04:23

**US3292103**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 10:55:50**

**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 16:04:23

**US3292103**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 10:55:50**

**Other**

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:04:23



US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:50

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:04:23

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:50

No Risk Identified

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	11 Aug 2020 16:04:23

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:50

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:04:23

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:50

**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 16:04:23

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:50

**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 16:04:23

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:50

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 16:04:23

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:50

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:04:23

**US3292103**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 10:55:50**

**Other**

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:04:23



US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:50

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:04:23

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:55:50**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:04:37

US3292103

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
User entered '08 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 16:04:37

US3292103

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Aug 2020 16:04:37

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:55:50**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	11 Aug 2020 16:04:37

US3292103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:50

What was the date of randomization? (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	08 Aug 2020 22:15:34

US3292103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:50

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 03:10:09
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:10:08
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Aug 2020 22:15:34
User entered '185367' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	08 Aug 2020 22:15:34

US3292103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:50

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	08 Aug 2020 22:15:34



US3292103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:50

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)	11 Aug 2020 16:04:55

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 10:55:50**

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:04:55

US3292103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:50

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:04:55

US3292103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:50

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:04:55

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 10:55:50**

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:04:55

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:55:50

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:43:09
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:06:40

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:55:50

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:43:09
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:06:40

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:55:50

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:43:09
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:06:40



US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:55:50

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:43:09
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:06:40

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:50

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Aug 2020 16:06:40

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:06:40

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 16:06:40

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '16:05'	(b) (4), (b) (6)	11 Aug 2020 16:06:40

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 16:05'	System	11 Aug 2020 16:06:40

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:50

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '037.0' C	(b) (4), (b) (6)	11 Aug 2020 16:06:40

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:50

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Aug 2020 16:06:40



US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:50

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:06:40

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '078'	(b) (4), (b) (6)	11 Aug 2020 16:06:40

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Aug 2020 16:06:40

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '012'	(b) (4), (b) (6)	11 Aug 2020 16:06:40

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Aug 2020 16:06:40

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 16:42:30
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 16:07:20
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	11 Aug 2020 16:06:40
User entered '159'	(b) (4), (b) (6)	11 Aug 2020 16:06:40

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 16:06:40

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '081'	(b) (4), (b) (6)	11 Aug 2020 16:06:40



**US3292103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 16:06:40

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:55:50

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:43:09
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:06:40

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:55:50

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:43:09
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:06:40

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:50

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Aug 2020 16:06:40

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:06:40

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 16:06:40

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:50

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 14:56:31
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'as per protocol post dose vitals can be measured after 30 minutes' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 16:07:34
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).		11 Aug 2020 16:06:40
User entered '18:55'	(b) (4), (b) (6)	11 Aug 2020 16:06:40

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:55:50**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 18:55'	System	11 Aug 2020 16:06:40



US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:50

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '037.1' C	(b) (4), (b) (6)	11 Aug 2020 16:06:40

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:50

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Aug 2020 16:06:40

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:50

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:06:40

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '084'	(b) (4), (b) (6)	11 Aug 2020 16:06:40

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:55:50**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Aug 2020 16:06:40

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '014'	(b) (4), (b) (6)	11 Aug 2020 16:06:40

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:55:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Aug 2020 16:06:40

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 16:57:04
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 19:54:19
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	11 Aug 2020 16:06:40
User entered '157'	(b) (4), (b) (6)	11 Aug 2020 16:06:40



**US3292103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:55:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 16:06:40

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '084'	(b) (4), (b) (6)	11 Aug 2020 16:06:40

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:55:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 16:06:40

US3292103

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 01:25:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:08:30

US3292103

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:50

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 01:25:46
User entered '08 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 16:08:30

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:55:50**

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Darlington Akahara (b) (4)	08 Aug 2020 23:39:00

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:55:50**

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Darlington Akahara (b) (4)	08 Aug 2020 23:39:00

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
User entered empty.	Darlington Akahara (b) (4)	08 Aug 2020 23:39:00



**US3292103**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:55:50**

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	08 Aug 2020 23:39:00

US3292103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:50

What was the treatment date? (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Aug 2020'	Darlington Akahara (b) (4)	08 Aug 2020 23:39:00

US3292103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:50

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '18:22'	Darlington Akahara (b) (4)	08 Aug 2020 23:39:00

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:55:50**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '8 Aug 2020 18:22'	System	08 Aug 2020 23:39:00

US3292103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:50

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Darlington Akahara (b) (4)	08 Aug 2020 23:39:00

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:55:50**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:55:50**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	08 Aug 2020 23:39:00

US3292103

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:08:49



US3292103

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 16:08:49

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:55:50**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '16:30'	(b) (4), (b) (6)	11 Aug 2020 16:08:49

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:55:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 16:30'	System	11 Aug 2020 16:08:49

US3292103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:55:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 16:09:06

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	11 Aug 2020 16:09:06

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:09:06

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:55:50**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
User entered '16:25'	(b) (4), (b) (6)	11 Aug 2020 16:09:06

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 16:25'	System	11 Aug 2020 16:09:06



**US3292103**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:55:50**

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	11 Aug 2020 16:09:06

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:55:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:09:06

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:55:50**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:09:06

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:55:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 16:09:06

US3292103

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:55:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:09:10

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 16:09:10

**US3292103**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 23:39:00

**US3292103**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:55:02', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '85c93d83-83ed-4794-bc95-acd42ca0ab0e'	System	08 Aug 2020 23:55:21
User entered 'Yes (Y)'	System	08 Aug 2020 23:55:21



**US3292103**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:55:08', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '85c93d83-83ed-4794-bc95-acd42ca0ab0e'	System	08 Aug 2020 23:55:21
User entered '98.7'	System	08 Aug 2020 23:55:21

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:55:14', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '85c93d83-83ed-4794-bc95-acd42ca0ab0e'	System	08 Aug 2020 23:55:21
User entered 'No (N)'	System	08 Aug 2020 23:55:21

**US3292103**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:55:20', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '85c93d83-83ed-4794-bc95-acd42ca0ab0e' User entered '08 Aug 2020 18:55'	System	08 Aug 2020 23:55:21
	System	08 Aug 2020 23:55:21

**US3292103**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 18:42'	System	08 Aug 2020 23:39:00

**US3292103**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 21:12'	System	08 Aug 2020 23:39:00

**US3292103**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 23:39:00

**US3292103**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:08:13', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '10ce8aeb-0a7e-47d7-bcc8-db930badb461'	System	09 Aug 2020 03:08:53
User entered 'Yes (Y)'	System	09 Aug 2020 03:08:53

**US3292103**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:08:23', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '10ce8aeb-0a7e-47d7-bcc8-db930badb461' User entered '97.3'	System	09 Aug 2020 03:08:53



**US3292103**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:08:28', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '10ce8aeb-0a7e-47d7-bcc8-db930badb461'	System	09 Aug 2020 03:08:53
User entered 'Yes (Y)'	System	09 Aug 2020 03:08:53

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'medication documented' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 15:37:07
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:08:49', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '10ce8aeb-0a7e-47d7-bcc8-db930badb461'	Victoria Hernandez (b) (4)	(b) (4) 17 Sep 2020 16:38:05
User entered '1'	System	09 Aug 2020 03:08:53

**US3292103**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:08:49', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '10ce8aeb-0a7e-47d7-bcc8-db930badb461'	System	09 Aug 2020 03:08:53
User entered '0'	System	09 Aug 2020 03:08:53

**US3292103**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:08:52', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '10ce8aeb-0a7e-47d7-bcc8-db930badb461'	System	09 Aug 2020 03:08:53
User entered '08 Aug 2020 22:08'	System	09 Aug 2020 03:08:53

**US3292103**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 22:07'	System	08 Aug 2020 23:39:00

**US3292103**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 23:39:00

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered 'Day 2'	System	08 Aug 2020 23:39:00

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:01:04', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '86527897-d01c-4da0-b461-dffedb5b1666'	System	09 Aug 2020 23:01:39
User entered 'Yes (Y)'	System	09 Aug 2020 23:01:39



**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:01:09', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '86527897-d01c-4da0-b461-dffedb5b1666'	System	09 Aug 2020 23:01:39
User entered '98.2'	System	09 Aug 2020 23:01:39

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:01:16', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '86527897-d01c-4da0-b461-dffedb5b1666'	System	09 Aug 2020 23:01:39
User entered 'Yes (Y)'	System	09 Aug 2020 23:01:39

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Medication documented' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 15:37:15
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:01:28', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '86527897-d01c-4da0-b461-dffedb5b1666'	Victoria Hernandez (b) (4)	(b) (4) 17 Sep 2020 16:38:42
User entered '1'	System	09 Aug 2020 23:01:39
	System	09 Aug 2020 23:01:39
	System	09 Aug 2020 23:01:39

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:01:28', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '86527897-d01c-4da0-b461-dffedb5b1666'	System	09 Aug 2020 23:01:39
User entered '0'	System	09 Aug 2020 23:01:39

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:01:37', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '86527897-d01c-4da0-b461-dffedb5b1666'	System	09 Aug 2020 23:01:39
User entered '09 Aug 2020 18:01'	System	09 Aug 2020 23:01:39

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 23:39:00

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 23:39:00

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered 'Day 3'	System	08 Aug 2020 23:39:00



**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:28:13', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '9a6eaaf2-cbe8-4e6c-ab43-75384ac8d27f'	System	10 Aug 2020 23:28:54
User entered 'Yes (Y)'	System	10 Aug 2020 23:28:54

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:28:21', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '9a6eaaf2-cbe8-4e6c-ab43-75384ac8d27f' User entered '98.0'	System	10 Aug 2020 23:28:54

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:28:25', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '9a6eaf2-cbe8-4e6c-ab43-75384ac8d27f'	System	10 Aug 2020 23:28:54
User entered 'Yes (Y)'	System	10 Aug 2020 23:28:54

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Medication documented' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 15:37:21
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:28:38', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '9a6eaaf2-cbe8-4e6c-ab43-75384ac8d27f' User entered '1'	Victoria Hernandez (b) (4)	17 Sep 2020 16:39:09
	System	10 Aug 2020 23:28:54
	System	10 Aug 2020 23:28:54
	System	10 Aug 2020 23:28:54

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:28:38', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '9a6eaaf2-cbe8-4e6c-ab43-75384ac8d27f' User entered '0'	System	10 Aug 2020 23:28:54

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:28:52', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '9a6eaaf2-cbe8-4e6c-ab43-75384ac8d27f' User entered '10 Aug 2020 18:28'	System	10 Aug 2020 23:28:54

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 23:39:00

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 23:39:00



**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered 'Day 4'	System	08 Aug 2020 23:39:00

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:57:15', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '90442d75-8bd9-4940-8352-5e62a6ac8d90'	System	11 Aug 2020 21:57:48
User entered 'Yes (Y)'	System	11 Aug 2020 21:57:48

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:57:21', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '90442d75-8bd9-4940-8352-5e62a6ac8d90'	System	11 Aug 2020 21:57:48
User entered '97.8'	System	11 Aug 2020 21:57:48

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:57:25', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '90442d75-8bd9-4940-8352-5e62a6ac8d90'	System	11 Aug 2020 21:57:48
User entered 'Yes (Y)'	System	11 Aug 2020 21:57:48

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Medication documented' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 15:37:27
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:57:32', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '90442d75-8bd9-4940-8352-5e62a6ac8d90'	Victoria Hernandez (b) (4)	17 Sep 2020 16:39:32
User entered '1'	System	11 Aug 2020 21:57:48
	System	11 Aug 2020 21:57:48
	System	11 Aug 2020 21:57:48

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:57:32', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '90442d75-8bd9-4940-8352-5e62a6ac8d90'	System	11 Aug 2020 21:57:48
User entered '0'	System	11 Aug 2020 21:57:48

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:57:43', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '90442d75-8bd9-4940-8352-5e62a6ac8d90'	System	11 Aug 2020 21:57:48
User entered '11 Aug 2020 16:57'	System	11 Aug 2020 21:57:48

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 23:39:00



**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 23:39:00

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered 'Day 5'	System	08 Aug 2020 23:39:00

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:33:21', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '36aeac65-24d6-4805-8244-ad16ee9944d7'	System	12 Aug 2020 22:33:55
User entered 'Yes (Y)'	System	12 Aug 2020 22:33:55

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:33:25', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '36aeac65-24d6-4805-8244-ad16ee9944d7'	System	12 Aug 2020 22:33:55
User entered '98.2'	System	12 Aug 2020 22:33:55

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:33:29', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '36aeac65-24d6-4805-8244-ad16ee9944d7'	System	12 Aug 2020 22:33:55
User entered 'Yes (Y)'	System	12 Aug 2020 22:33:55

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Medication documented' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 15:37:33
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:33:44', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '36aeac65-24d6-4805-8244-ad16ee9944d7'	Victoria Hernandez (b) (4)	(b) (4) 17 Sep 2020 16:39:57
User entered '1'	System	12 Aug 2020 22:33:55
	System	12 Aug 2020 22:33:55
	System	12 Aug 2020 22:33:55

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:33:44', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '36aeac65-24d6-4805-8244-ad16ee9944d7'	System	12 Aug 2020 22:33:55
User entered '0'	System	12 Aug 2020 22:33:55

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:33:51', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '36aeac65-24d6-4805-8244-ad16ee9944d7'	System	12 Aug 2020 22:33:55
User entered '12 Aug 2020 17:33'	System	12 Aug 2020 22:33:55



**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 23:39:00

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 23:39:00

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered 'Day 6'	System	08 Aug 2020 23:39:00

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:23:42', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '9f7a7663-cd38-48cb-8d57-f5f68b56981c'	System	13 Aug 2020 22:24:14
User entered 'Yes (Y)'	System	13 Aug 2020 22:24:14

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:23:47', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '9f7a7663-cd38-48cb-8d57-f5f68b56981c'	System	13 Aug 2020 22:24:14
User entered '98.0'	System	13 Aug 2020 22:24:14

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:23:50', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '9f7a7663-cd38-48cb-8d57-f5f68b56981c'	System	13 Aug 2020 22:24:14
User entered 'Yes (Y)'	System	13 Aug 2020 22:24:14

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Medication documented' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 15:37:39
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:24:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '9f7a7663-cd38-48cb-8d57-f5f68b56981c'	Victoria Hernandez (b) (4)	17 Sep 2020 16:40:19
User entered '1'	System	13 Aug 2020 22:24:14
	System	13 Aug 2020 22:24:14
	System	13 Aug 2020 22:24:14

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:24:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '9f7a7663-cd38-48cb-8d57-f5f68b56981c' User entered '0'	System	13 Aug 2020 22:24:14



**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:24:09', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '9f7a7663-cd38-48cb-8d57-f5f68b56981c' User entered '13 Aug 2020 17:24'	System	13 Aug 2020 22:24:14
	System	13 Aug 2020 22:24:14

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 23:39:00

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 23:39:00

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered 'Day 7'	System	08 Aug 2020 23:39:00

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:50:44', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c7ee065a-c3d9-40fc-91d5-b4a26e906b7b'	System	14 Aug 2020 21:51:11
User entered 'Yes (Y)'	System	14 Aug 2020 21:51:11

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:50:49', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c7ee065a-c3d9-40fc-91d5-b4a26e906b7b'	System	14 Aug 2020 21:51:11
User entered '98.0'	System	14 Aug 2020 21:51:11

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:50:54', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c7ee065a-c3d9-40fc-91d5-b4a26e906b7b'	System	14 Aug 2020 21:51:11
User entered 'Yes (Y)'	System	14 Aug 2020 21:51:11

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Medication documented' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 15:37:45
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:51:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c7ee065a-c3d9-40fc-91d5-b4a26e906b7b'	Victoria Hernandez (b) (4)	17 Sep 2020 16:41:17
User entered '1'	System	14 Aug 2020 21:51:11
	System	14 Aug 2020 21:51:11
	System	14 Aug 2020 21:51:11



**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:51:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c7ee065a-c3d9-40fc-91d5-b4a26e906b7b'	System	14 Aug 2020 21:51:11
User entered '0'	System	14 Aug 2020 21:51:11

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:51:09', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c7ee065a-c3d9-40fc-91d5-b4a26e906b7b' User entered '14 Aug 2020 16:51'	System	14 Aug 2020 21:51:11
	System	14 Aug 2020 21:51:11

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 23:39:00

**US3292103**

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

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

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 23:39:00

**US3292103**

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

**Form: Temperature\_Day(8)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 22:24:14
User entered 'Day 8'	System	13 Aug 2020 22:24:14

**US3292103**

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

**Form: Temperature\_Day(8)**

**Generated On: 26 Nov 2020 10:55:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-15T15:58:02', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'e61d320d-9a1e-4126-ba05-ab9b9a7d04ac'	System	15 Aug 2020 20:58:29
User entered 'Yes (Y)'	System	15 Aug 2020 20:58:29

**US3292103**

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

**Form: Temperature\_Day(8)**

**Generated On: 26 Nov 2020 10:55:50**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-15T15:58:07', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'e61d320d-9a1e-4126-ba05-ab9b9a7d04ac'	System	15 Aug 2020 20:58:29
User entered '97.8'	System	15 Aug 2020 20:58:29

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-15T15:58:11', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'e61d320d-9a1e-4126-ba05-ab9b9a7d04ac'	System	15 Aug 2020 20:58:29
User entered 'Yes (Y)'	System	15 Aug 2020 20:58:29



US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Medication documented' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 15:37:52
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-15T15:58:15', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'e61d320d-9a1e-4126-ba05-ab9b9a7d04ac'	Victoria Hernandez (b) (4)	17 Sep 2020 16:41:49
User entered '1'	System	15 Aug 2020 20:58:29
	System	15 Aug 2020 20:58:29
	System	15 Aug 2020 20:58:29

**US3292103**

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

**Form: Temperature\_Day(8)**

**Generated On: 26 Nov 2020 10:55:50**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-15T15:58:15', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'e61d320d-9a1e-4126-ba05-ab9b9a7d04ac'	System	15 Aug 2020 20:58:29
User entered '0'	System	15 Aug 2020 20:58:29

**US3292103**

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

**Form: Temperature\_Day(8)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-15T15:58:25', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'e61d320d-9a1e-4126-ba05-ab9b9a7d04ac'	System	15 Aug 2020 20:58:29
User entered '15 Aug 2020 15:58'	System	15 Aug 2020 20:58:29

**US3292103**

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

**Form: Temperature\_Day(8)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 22:24:14

**US3292103**

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

**Form: Temperature\_Day(8)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 22:24:14

**US3292103**

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

**Form: Temperature\_Day(9)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 21:51:11
User entered 'Day 9'	System	14 Aug 2020 21:51:11

**US3292103**

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

**Form: Temperature\_Day(9)**

**Generated On: 26 Nov 2020 10:55:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-16T15:16:16', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'de3fe81b-073a-4580-b016-83b59353787a'	System	16 Aug 2020 20:16:46
User entered 'Yes (Y)'	System	16 Aug 2020 20:16:46

**US3292103**

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

**Form: Temperature\_Day(9)**

**Generated On: 26 Nov 2020 10:55:50**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-16T15:16:23', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'de3fe81b-073a-4580-b016-83b59353787a'	System	16 Aug 2020 20:16:46
User entered '96.8'	System	16 Aug 2020 20:16:46



**US3292103**

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

**Form: Temperature\_Day(9)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-16T15:16:27', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'de3fe81b-073a-4580-b016-83b59353787a'	System	16 Aug 2020 20:16:46
User entered 'Yes (Y)'	System	16 Aug 2020 20:16:46

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Medication documented' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 15:37:57
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-16T15:16:32', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'de3fe81b-073a-4580-b016-83b59353787a' User entered '1'	Victoria Hernandez (b) (4)	17 Sep 2020 16:42:48
	System	16 Aug 2020 20:16:46
	System	16 Aug 2020 20:16:46
	System	16 Aug 2020 20:16:46

**US3292103**

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

**Form: Temperature\_Day(9)**

**Generated On: 26 Nov 2020 10:55:50**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-16T15:16:32', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'de3fe81b-073a-4580-b016-83b59353787a' User entered '0'	System	16 Aug 2020 20:16:46

**US3292103**

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

**Form: Temperature\_Day(9)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-16T15:16:42', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'de3fe81b-073a-4580-b016-83b59353787a'	System	16 Aug 2020 20:16:46
User entered '16 Aug 2020 15:16'	System	16 Aug 2020 20:16:46

**US3292103**

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

**Form: Temperature\_Day(9)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 21:51:11

**US3292103**

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

**Form: Temperature\_Day(9)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 21:51:11

**US3292103**

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

**Form: Temperature\_Day(10)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:58:29
User entered 'Day 10'	System	15 Aug 2020 20:58:29

**US3292103**

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

**Form: Temperature\_Day(10)**

**Generated On: 26 Nov 2020 10:55:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-17T14:18:04', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '646e03b7-d423-4710-a5b7-22469d42e5e1'	System	17 Aug 2020 19:18:29
User entered 'Yes (Y)'	System	17 Aug 2020 19:18:29



**US3292103**

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

**Form: Temperature\_Day(10)**

**Generated On: 26 Nov 2020 10:55:50**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-17T14:18:09', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '646e03b7-d423-4710-a5b7-22469d42e5e1'	System	17 Aug 2020 19:18:29
User entered '97.7'	System	17 Aug 2020 19:18:29

**US3292103**

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

**Form: Temperature\_Day(10)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-17T14:18:13', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '646e03b7-d423-4710-a5b7-22469d42e5e1'	System	17 Aug 2020 19:18:29
User entered 'Yes (Y)'	System	17 Aug 2020 19:18:29

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Medication documented' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 15:38:05
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-17T14:18:20', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '646e03b7-d423-4710-a5b7-22469d42e5e1'	Victoria Hernandez (b) (4)	17 Sep 2020 16:43:13
User entered '1'	System	17 Aug 2020 19:18:29
	System	17 Aug 2020 19:18:29
	System	17 Aug 2020 19:18:29

**US3292103**

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

**Form: Temperature\_Day(10)**

**Generated On: 26 Nov 2020 10:55:50**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-17T14:18:20', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '646e03b7-d423-4710-a5b7-22469d42e5e1'	System	17 Aug 2020 19:18:29
User entered '0'	System	17 Aug 2020 19:18:29

**US3292103**

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

**Form: Temperature\_Day(10)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-17T14:18:26', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '646e03b7-d423-4710-a5b7-22469d42e5e1'	System	17 Aug 2020 19:18:29
User entered '17 Aug 2020 14:18'	System	17 Aug 2020 19:18:29

**US3292103**

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

**Form: Temperature\_Day(10)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	15 Aug 2020 20:58:29

**US3292103**

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

**Form: Temperature\_Day(10)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	15 Aug 2020 20:58:29

**US3292103**

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

**Form: Temperature\_Day(11)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 20:16:46
User entered 'Day 11'	System	16 Aug 2020 20:16:46



**US3292103**

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

**Form: Temperature\_Day(11)**

**Generated On: 26 Nov 2020 10:55:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-18T16:07:03', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'caaec2f6-c780-4ad3-86a8-08ee88f0eaf7'	System	18 Aug 2020 21:07:24
User entered 'Yes (Y)'	System	18 Aug 2020 21:07:24

**US3292103**

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

**Form: Temperature\_Day(11)**

**Generated On: 26 Nov 2020 10:55:50**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-18T16:07:07', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'caaec2f6-c780-4ad3-86a8-08ee88f0eaf7'	System	18 Aug 2020 21:07:24
User entered '98.2'	System	18 Aug 2020 21:07:24

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-18T16:07:12', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'caaec2f6-c780-4ad3-86a8-08ee88f0eaf7'	System	18 Aug 2020 21:07:24
User entered 'Yes (Y)'	System	18 Aug 2020 21:07:24

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Medication documented' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 15:38:12
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-18T16:07:15', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'caaec2f6-c780-4ad3-86a8-08ee88f0eaf7'	Victoria Hernandez (b) (4)	(b) (4) 17 Sep 2020 16:43:38
User entered '1'	System	18 Aug 2020 21:07:24
	System	18 Aug 2020 21:07:24
	System	18 Aug 2020 21:07:24

**US3292103**

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

**Form: Temperature\_Day(11)**

**Generated On: 26 Nov 2020 10:55:50**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-18T16:07:15', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'caaec2f6-c780-4ad3-86a8-08ee88f0eaf7' User entered '0'	System	18 Aug 2020 21:07:24

**US3292103**

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

**Form: Temperature\_Day(11)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-18T16:07:22', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'caaec2f6-c780-4ad3-86a8-08ee88f0eaf7'	System	18 Aug 2020 21:07:24
User entered '18 Aug 2020 16:07'	System	18 Aug 2020 21:07:24

**US3292103**

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

**Form: Temperature\_Day(11)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 20:16:46

**US3292103**

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

**Form: Temperature\_Day(11)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 20:16:46



**US3292103**

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

**Form: Temperature\_Day(12)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 19:18:29
User entered 'Day 12'	System	17 Aug 2020 19:18:29

**US3292103**

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

**Form: Temperature\_Day(12)**

**Generated On: 26 Nov 2020 10:55:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-19T18:17:36', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '483186a3-ab3c-434e-a9f6-6bad6f169481'	System	19 Aug 2020 23:17:53
User entered 'Yes (Y)'	System	19 Aug 2020 23:17:53

**US3292103**

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

**Form: Temperature\_Day(12)**

**Generated On: 26 Nov 2020 10:55:50**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-19T18:17:40', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '483186a3-ab3c-434e-a9f6-6bad6f169481'	System	19 Aug 2020 23:17:53
User entered '98.2'	System	19 Aug 2020 23:17:53

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-19T18:17:42', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '483186a3-ab3c-434e-a9f6-6bad6f169481'	System	19 Aug 2020 23:17:53
User entered 'Yes (Y)'	System	19 Aug 2020 23:17:53

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Medication documented' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 15:38:17
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-19T18:17:47', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '483186a3-ab3c-434e-a9f6-6bad6f169481'	Victoria Hernandez (b) (4)	17 Sep 2020 16:44:07
User entered '1'	System	19 Aug 2020 23:17:53
	System	19 Aug 2020 23:17:53
	System	19 Aug 2020 23:17:53

**US3292103**

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

**Form: Temperature\_Day(12)**

**Generated On: 26 Nov 2020 10:55:50**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-19T18:17:47', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '483186a3-ab3c-434e-a9f6-6bad6f169481'	System	19 Aug 2020 23:17:53
User entered '0'	System	19 Aug 2020 23:17:53

**US3292103**

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

**Form: Temperature\_Day(12)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-19T18:17:52', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '483186a3-ab3c-434e-a9f6-6bad6f169481'	System	19 Aug 2020 23:17:53
User entered '19 Aug 2020 18:17'	System	19 Aug 2020 23:17:53

**US3292103**

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

**Form: Temperature\_Day(12)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 19:18:29



**US3292103**

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

**Form: Temperature\_Day(12)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 19:18:29

**US3292103**

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

**Form: Temperature\_Day(13)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 21:07:24
User entered 'Day 13'	System	18 Aug 2020 21:07:24

**US3292103**

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

**Form: Temperature\_Day(13)**

**Generated On: 26 Nov 2020 10:55:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-20T15:24:18', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '62a303d0-20a4-4b02-812b-1b6a6a422a30'	System	20 Aug 2020 20:24:42
User entered 'Yes (Y)'	System	20 Aug 2020 20:24:42

**US3292103**

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

**Form: Temperature\_Day(13)**

**Generated On: 26 Nov 2020 10:55:50**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-20T15:24:21', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '62a303d0-20a4-4b02-812b-1b6a6a422a30'	System	20 Aug 2020 20:24:42
User entered '98.0'	System	20 Aug 2020 20:24:42

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-20T15:24:31', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '62a303d0-20a4-4b02-812b-1b6a6a422a30'	System	20 Aug 2020 20:24:42
User entered 'Yes (Y)'	System	20 Aug 2020 20:24:42

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Medication documented' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 15:38:22
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-20T15:24:34', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '62a303d0-20a4-4b02-812b-1b6a6a422a30'	Victoria Hernandez (b) (4)	17 Sep 2020 16:44:31
User entered '1'	System	20 Aug 2020 20:24:42
	System	20 Aug 2020 20:24:42
	System	20 Aug 2020 20:24:42

**US3292103**

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

**Form: Temperature\_Day(13)**

**Generated On: 26 Nov 2020 10:55:50**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-20T15:24:34', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '62a303d0-20a4-4b02-812b-1b6a6a422a30'	System	20 Aug 2020 20:24:42
User entered '0'	System	20 Aug 2020 20:24:42

**US3292103**

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

**Form: Temperature\_Day(13)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-20T15:24:37', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '62a303d0-20a4-4b02-812b-1b6a6a422a30'	System	20 Aug 2020 20:24:42
User entered '20 Aug 2020 15:24'	System	20 Aug 2020 20:24:42



**US3292103**

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

**Form: Temperature\_Day(13)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 21:07:24

**US3292103**

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

**Form: Temperature\_Day(13)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 21:07:24

**US3292103**

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

**Form: Temperature\_Day(14)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 23:17:53
User entered 'Day 14'	System	19 Aug 2020 23:17:53

**US3292103**

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

**Form: Temperature\_Day(14)**

**Generated On: 26 Nov 2020 10:55:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-21T23:59:32', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '163b76c2-9c7d-4903-b68a-0735e4e21ede'	System	22 Aug 2020 04:59:53
User entered 'Yes (Y)'	System	22 Aug 2020 04:59:53

**US3292103**

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

**Form: Temperature\_Day(14)**

**Generated On: 26 Nov 2020 10:55:50**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-21T23:59:39', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '163b76c2-9c7d-4903-b68a-0735e4e21ede'	System	22 Aug 2020 04:59:53
User entered '98.2'	System	22 Aug 2020 04:59:53

**US3292103**

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

**Form: Temperature\_Day(14)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-21T23:59:43', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '163b76c2-9c7d-4903-b68a-0735e4e21ede'	System	22 Aug 2020 04:59:53
User entered 'Yes (Y)'	System	22 Aug 2020 04:59:53

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Medication documented' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 15:38:28
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-21T23:59:47', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '163b76c2-9c7d-4903-b68a-0735e4e21ede' User entered '1'	Victoria Hernandez (b) (4)	17 Sep 2020 16:44:56
	System	22 Aug 2020 04:59:53
	System	22 Aug 2020 04:59:53
	System	22 Aug 2020 04:59:53

**US3292103**

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

**Form: Temperature\_Day(14)**

**Generated On: 26 Nov 2020 10:55:50**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-21T23:59:47', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '163b76c2-9c7d-4903-b68a-0735e4e21ede' User entered '0'	System	22 Aug 2020 04:59:53



**US3292103**

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

**Form: Temperature\_Day(14)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-21T23:59:51', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '163b76c2-9c7d-4903-b68a-0735e4e21ede'	System	22 Aug 2020 04:59:53
User entered '21 Aug 2020 23:59'	System	22 Aug 2020 04:59:53

**US3292103**

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

**Form: Temperature\_Day(14)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 23:17:53

**US3292103**

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

**Form: Temperature\_Day(14)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 23:17:53

**US3292103**

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

**Form: Temperature\_Day(15)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:24:42
User entered 'Day 15'	System	20 Aug 2020 20:24:42

**US3292103**

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

**Form: Temperature\_Day(15)**

**Generated On: 26 Nov 2020 10:55:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-22T17:12:20', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '05a8f84d-8ca9-4c96-835e-868e6fe23626'	System	22 Aug 2020 22:12:40
User entered 'Yes (Y)'	System	22 Aug 2020 22:12:40

**US3292103**

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

**Form: Temperature\_Day(15)**

**Generated On: 26 Nov 2020 10:55:50**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-22T17:12:25', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '05a8f84d-8ca9-4c96-835e-868e6fe23626'	System	22 Aug 2020 22:12:40
User entered '98.0'	System	22 Aug 2020 22:12:40

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-22T17:12:31', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '05a8f84d-8ca9-4c96-835e-868e6fe23626'	System	22 Aug 2020 22:12:40
User entered 'Yes (Y)'	System	22 Aug 2020 22:12:40

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Medication documented' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 15:38:36
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-22T17:12:35', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '05a8f84d-8ca9-4c96-835e-868e6fe23626'	Victoria Hernandez (b) (4)	17 Sep 2020 16:45:25
User entered '1'	System	22 Aug 2020 22:12:40
	System	22 Aug 2020 22:12:40
	System	22 Aug 2020 22:12:40



**US3292103**

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

**Form: Temperature\_Day(15)**

**Generated On: 26 Nov 2020 10:55:50**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-22T17:12:35', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '05a8f84d-8ca9-4c96-835e-868e6fe23626'	System	22 Aug 2020 22:12:40
User entered '0'	System	22 Aug 2020 22:12:40

**US3292103**

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

**Form: Temperature\_Day(15)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-22T17:12:38', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '05a8f84d-8ca9-4c96-835e-868e6fe23626'	System	22 Aug 2020 22:12:40
User entered '22 Aug 2020 17:12'	System	22 Aug 2020 22:12:40

**US3292103**

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

**Form: Temperature\_Day(15)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 20:24:42

**US3292103**

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

**Form: Temperature\_Day(15)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 20:24:42

**US3292103**

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

**Form: Temperature\_Day(16)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	22 Aug 2020 04:59:53
User entered 'Day 16'	System	22 Aug 2020 04:59:53

**US3292103**

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

**Form: Temperature\_Day(16)**

**Generated On: 26 Nov 2020 10:55:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-23T16:06:46', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a45bcff7-d86c-4a14-8841-bda1d6d90998'	System	23 Aug 2020 21:07:05
User entered 'Yes (Y)'	System	23 Aug 2020 21:07:05

**US3292103**

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

**Form: Temperature\_Day(16)**

**Generated On: 26 Nov 2020 10:55:50**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-23T16:06:50', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a45bcff7-d86c-4a14-8841-bda1d6d90998'	System	23 Aug 2020 21:07:05
User entered '97.5'	System	23 Aug 2020 21:07:05

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(16)

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-23T16:06:53', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a45bcff7-d86c-4a14-8841-bda1d6d90998'	System	23 Aug 2020 21:07:05
User entered 'Yes (Y)'	System	23 Aug 2020 21:07:05



US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(16)

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Medication documented' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 15:38:41
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-23T16:06:58', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a45bcff7-d86c-4a14-8841-bda1d6d90998'	Victoria Hernandez (b) (4)	17 Sep 2020 16:46:01
User entered '1'	System	23 Aug 2020 21:07:05

**US3292103**

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

**Form: Temperature\_Day(16)**

**Generated On: 26 Nov 2020 10:55:50**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-23T16:06:58', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a45bcff7-d86c-4a14-8841-bda1d6d90998'	System	23 Aug 2020 21:07:05
User entered '0'	System	23 Aug 2020 21:07:05

**US3292103**

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

**Form: Temperature\_Day(16)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-23T16:07:01', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a45bcff7-d86c-4a14-8841-bda1d6d90998'	System	23 Aug 2020 21:07:05
User entered '23 Aug 2020 16:07'	System	23 Aug 2020 21:07:05

**US3292103**

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

**Form: Temperature\_Day(16)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 04:59:53

**US3292103**

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

**Form: Temperature\_Day(16)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 04:59:53

**US3292103**

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

**Form: Temperature\_Day(17)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	22 Aug 2020 22:12:40
User entered 'Day 17'	System	22 Aug 2020 22:12:40

**US3292103**

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

**Form: Temperature\_Day(17)**

**Generated On: 26 Nov 2020 10:55:50**

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-24T14:54:21', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '18cd1812-9248-4281-9152-6b92c0db554a'	System	24 Aug 2020 19:54:36
User entered 'Yes (Y)'	System	24 Aug 2020 19:54:36

**US3292103**

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

**Form: Temperature\_Day(17)**

**Generated On: 26 Nov 2020 10:55:50**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-24T14:54:25', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '18cd1812-9248-4281-9152-6b92c0db554a'	System	24 Aug 2020 19:54:36
User entered '97.5'	System	24 Aug 2020 19:54:36



**US3292103**

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

**Form: Temperature\_Day(17)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-24T14:54:27', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '18cd1812-9248-4281-9152-6b92c0db554a'	System	24 Aug 2020 19:54:36
User entered 'No (N)'	System	24 Aug 2020 19:54:36

**US3292103**

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

**Form: Temperature\_Day(17)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-24T14:54:32', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '18cd1812-9248-4281-9152-6b92c0db554a'	System	24 Aug 2020 19:54:36
User entered '24 Aug 2020 14:54'	System	24 Aug 2020 19:54:36

**US3292103**

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

**Form: Temperature\_Day(17)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 22:12:40

**US3292103**

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

**Form: Temperature\_Day(17)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 22:12:40

**US3292103**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 23:39:00

**US3292103**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

[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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:55:26', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1f075399-396e-4a81-b25c-6b180fb9affb'	System	08 Aug 2020 23:55:40
User entered 'None (1)'	System	08 Aug 2020 23:55:40

**US3292103**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:55:29', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1f075399-396e-4a81-b25c-6b180fb9affb'	System	08 Aug 2020 23:55:40
User entered 'No (N)'	System	08 Aug 2020 23:55:40

**US3292103**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:55:32', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1f075399-396e-4a81-b25c-6b180fb9affb'	System	08 Aug 2020 23:55:40
User entered 'No (N)'	System	08 Aug 2020 23:55:40



US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:55:50

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:55:36', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1f075399-396e-4a81-b25c-6b180fb9affb'	System	08 Aug 2020 23:55:40
User entered 'None (1)'	System	08 Aug 2020 23:55:40

**US3292103**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:55:38', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1f075399-396e-4a81-b25c-6b180fb9affb'	System	08 Aug 2020 23:55:40
User entered '08 Aug 2020 18:55'	System	08 Aug 2020 23:55:40

**US3292103**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 18:42'	System	08 Aug 2020 23:39:00

**US3292103**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 21:12'	System	08 Aug 2020 23:39:00

**US3292103**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 23:39:00

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:55:50

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:09:01', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b976b5f3-828b-4f82-b925-99a6cd823239'	System	09 Aug 2020 03:09:44
User entered 'Does not interfere with activity (2)'	System	09 Aug 2020 03:09:44

**US3292103**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:09:24', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b976b5f3-828b-4f82-b925-99a6cd823239'	System	09 Aug 2020 03:09:44
User entered 'No (N)'	System	09 Aug 2020 03:09:44

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:55:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:09:32', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b976b5f3-828b-4f82-b925-99a6cd823239'	System	09 Aug 2020 03:09:44
User entered 'No (N)'	System	09 Aug 2020 03:09:44



US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:55:50

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:09:38', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b976b5f3-828b-4f82-b925-99a6cd823239'	System	09 Aug 2020 03:09:44
User entered 'None (1)'	System	09 Aug 2020 03:09:44

**US3292103**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:09:43', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b976b5f3-828b-4f82-b925-99a6cd823239'	System	09 Aug 2020 03:09:44
User entered '08 Aug 2020 22:09'	System	09 Aug 2020 03:09:44

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 22:07'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered 'Day 2'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

[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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:01:51', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'ce3ad959-defa-4917-83a9-374a358c6105'	System	09 Aug 2020 23:02:14
User entered 'Does not interfere with activity (2)'	System	09 Aug 2020 23:02:14

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:01:54', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'ce3ad959-defa-4917-83a9-374a358c6105'	System	09 Aug 2020 23:02:14
User entered 'No (N)'	System	09 Aug 2020 23:02:14

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:01:57', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'ce3ad959-defa-4917-83a9-374a358c6105'	System	09 Aug 2020 23:02:14
User entered 'No (N)'	System	09 Aug 2020 23:02:14



US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:55:50

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:02:03', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'ce3ad959-defa-4917-83a9-374a358c6105'	System	09 Aug 2020 23:02:14
User entered 'None (1)'	System	09 Aug 2020 23:02:14

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:02:13', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'ce3ad959-defa-4917-83a9-374a358c6105'	System	09 Aug 2020 23:02:14
User entered '09 Aug 2020 18:02'	System	09 Aug 2020 23:02:14

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered 'Day 3'	System	08 Aug 2020 23:39:00

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:55:50

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:29:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '24272b2e-4d7e-47a9-ad5c-401a57cdbel1a'	System	10 Aug 2020 23:29:46
User entered 'Does not interfere with activity (2)'	System	10 Aug 2020 23:29:46

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:29:15', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '24272b2e-4d7e-47a9-ad5c-401a57cdbel1a'	System	10 Aug 2020 23:29:46
User entered 'No (N)'	System	10 Aug 2020 23:29:46

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:29:27', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '24272b2e-4d7e-47a9-ad5c-401a57cdbel1a'	System	10 Aug 2020 23:29:46
User entered 'No (N)'	System	10 Aug 2020 23:29:46



US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:55:50

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:29:34', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '24272b2e-4d7e-47a9-ad5c-401a57cdbel1a' User entered 'None (1)'	System	10 Aug 2020 23:29:46
	System	10 Aug 2020 23:29:46

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:29:43', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '24272b2e-4d7e-47a9-ad5c-401a57cdbel1a'	System	10 Aug 2020 23:29:46
User entered '10 Aug 2020 18:29'	System	10 Aug 2020 23:29:46

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered 'Day 4'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

[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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:57:52', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '45f1a826-f479-4739-8e51-bed763370c9a'	System	11 Aug 2020 21:58:13
User entered 'None (1)'	System	11 Aug 2020 21:58:13

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:57:55', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '45f1a826-f479-4739-8e51-bed763370c9a'	System	11 Aug 2020 21:58:13
User entered 'No (N)'	System	11 Aug 2020 21:58:13

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:57:58', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '45f1a826-f479-4739-8e51-bed763370c9a'	System	11 Aug 2020 21:58:13
User entered 'No (N)'	System	11 Aug 2020 21:58:13



**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:58:01', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '45f1a826-f479-4739-8e51-bed763370c9a'	System	11 Aug 2020 21:58:13
User entered 'None (1)'	System	11 Aug 2020 21:58:13

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:58:11', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '45f1a826-f479-4739-8e51-bed763370c9a'	System	11 Aug 2020 21:58:13
User entered '11 Aug 2020 16:58'	System	11 Aug 2020 21:58:13

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered 'Day 5'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

[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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:34:06', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b49ac9e3-964f-4995-8285-9c3e24983779'	System	12 Aug 2020 22:34:30
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 22:34:30

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:34:09', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b49ac9e3-964f-4995-8285-9c3e24983779'	System	12 Aug 2020 22:34:30
User entered 'No (N)'	System	12 Aug 2020 22:34:30

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:34:12', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b49ac9e3-964f-4995-8285-9c3e24983779'	System	12 Aug 2020 22:34:30
User entered 'No (N)'	System	12 Aug 2020 22:34:30



**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:34:15', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b49ac9e3-964f-4995-8285-9c3e24983779'	System	12 Aug 2020 22:34:30
User entered 'None (1)'	System	12 Aug 2020 22:34:30

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:34:28', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b49ac9e3-964f-4995-8285-9c3e24983779' User entered '12 Aug 2020 17:34'	System	12 Aug 2020 22:34:30
	System	12 Aug 2020 22:34:30

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered 'Day 6'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

[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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:24:20', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '0cbe2d1e-de5c-4ed2-9093-bff0bbaeb8ac'	System	13 Aug 2020 22:24:35
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 22:24:35

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:24:23', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '0cbe2d1e-de5c-4ed2-9093-bff0bbaeb8ac'	System	13 Aug 2020 22:24:35
User entered 'No (N)'	System	13 Aug 2020 22:24:35

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:24:26', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '0cbe2d1e-de5c-4ed2-9093-bff0bbaeb8ac'	System	13 Aug 2020 22:24:35
User entered 'No (N)'	System	13 Aug 2020 22:24:35



**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

[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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:24:29', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '0cbe2d1e-de5c-4ed2-9093-bff0bbaeb8ac'	System	13 Aug 2020 22:24:35
User entered 'None (1)'	System	13 Aug 2020 22:24:35

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:24:32', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '0cbe2d1e-de5c-4ed2-9093-bff0bbaeb8ac'	System	13 Aug 2020 22:24:35
User entered '13 Aug 2020 17:24'	System	13 Aug 2020 22:24:35

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered 'Day 7'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

[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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:51:14', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '933035ac-ac0b-418b-8eba-03078a638ab6'	System	14 Aug 2020 21:51:35
User entered 'None (1)'	System	14 Aug 2020 21:51:35

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:51:18', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '933035ac-ac0b-418b-8eba-03078a638ab6'	System	14 Aug 2020 21:51:35
User entered 'No (N)'	System	14 Aug 2020 21:51:35

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:51:22', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '933035ac-ac0b-418b-8eba-03078a638ab6'	System	14 Aug 2020 21:51:35
User entered 'No (N)'	System	14 Aug 2020 21:51:35



**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:51:26', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '933035ac-ac0b-418b-8eba-03078a638ab6'	System	14 Aug 2020 21:51:35
User entered 'None (1)'	System	14 Aug 2020 21:51:35

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:51:32', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '933035ac-ac0b-418b-8eba-03078a638ab6' User entered '14 Aug 2020 16:51'	System	14 Aug 2020 21:51:35
	System	14 Aug 2020 21:51:35

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:55:42', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bb027e5-1bb4-4b6a-abfc-921889c1d06f'	System	08 Aug 2020 23:56:10
User entered 'None (0)'	System	08 Aug 2020 23:56:10

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:55:45', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bb027e5-1bb4-4b6a-abfc-921889c1d06f'	System	08 Aug 2020 23:56:10
User entered 'None (0)'	System	08 Aug 2020 23:56:10

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:55:47', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bb027e5-1bb4-4b6a-abfc-921889c1d06f'	System	08 Aug 2020 23:56:10
User entered 'None (0)'	System	08 Aug 2020 23:56:10



**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:55:50', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bb027e5-1bb4-4b6a-abfc-921889c1d06f'	System	08 Aug 2020 23:56:10
User entered 'None (0)'	System	08 Aug 2020 23:56:10

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:55:52', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bb027e5-1bb4-4b6a-abfc-921889c1d06f'	System	08 Aug 2020 23:56:10
User entered 'None (0)'	System	08 Aug 2020 23:56:10

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:55:54', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bb027e5-1bb4-4b6a-abfc-921889c1d06f'	System	08 Aug 2020 23:56:10
User entered 'None (0)'	System	08 Aug 2020 23:56:10

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:56:04', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bb027e5-1bb4-4b6a-abfc-921889c1d06f'	System	08 Aug 2020 23:56:10
User entered 'No (N)'	System	08 Aug 2020 23:56:10

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:56:08', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bb027e5-1bb4-4b6a-abfc-921889c1d06f'	System	08 Aug 2020 23:56:10
User entered '08 Aug 2020 18:56'	System	08 Aug 2020 23:56:10

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 18:42'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 21:12'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 23:39:00



**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:09:48', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd74306c0-8692-4d17-ab23-6bcb82389101'	System	09 Aug 2020 03:10:10
User entered 'None (0)'	System	09 Aug 2020 03:10:10

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:09:50', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd74306c0-8692-4d17-ab23-6bcb82389101'	System	09 Aug 2020 03:10:10
User entered 'None (0)'	System	09 Aug 2020 03:10:10

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:09:53', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd74306c0-8692-4d17-ab23-6bcb82389101'	System	09 Aug 2020 03:10:10
User entered 'None (0)'	System	09 Aug 2020 03:10:10

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:09:56', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd74306c0-8692-4d17-ab23-6bcb82389101'	System	09 Aug 2020 03:10:10
User entered 'None (0)'	System	09 Aug 2020 03:10:10

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:09:58', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd74306c0-8692-4d17-ab23-6bcb82389101'	System	09 Aug 2020 03:10:10
User entered 'None (0)'	System	09 Aug 2020 03:10:10

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:10:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd74306c0-8692-4d17-ab23-6bcb82389101'	System	09 Aug 2020 03:10:10
User entered 'None (0)'	System	09 Aug 2020 03:10:10

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:10:04', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd74306c0-8692-4d17-ab23-6bcb82389101'	System	09 Aug 2020 03:10:10
User entered 'No (N)'	System	09 Aug 2020 03:10:10

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:10:07', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd74306c0-8692-4d17-ab23-6bcb82389101'	System	09 Aug 2020 03:10:10
User entered '08 Aug 2020 22:10'	System	09 Aug 2020 03:10:10



**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 22:07'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered 'Day 2'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:02:20', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '044af38d-2b62-4b66-844e-daa9621bf54a'	System	09 Aug 2020 23:03:14
User entered 'No interference with activity (1)'	System	09 Aug 2020 23:03:14

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:02:26', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '044af38d-2b62-4b66-844e-daa9621bf54a'	System	09 Aug 2020 23:03:14
User entered 'Some interference with activity (2)'	System	09 Aug 2020 23:03:14

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:02:30', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '044af38d-2b62-4b66-844e-daa9621bf54a'	System	09 Aug 2020 23:03:14
User entered 'None (0)'	System	09 Aug 2020 23:03:14

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:02:34', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '044af38d-2b62-4b66-844e-daa9621bf54a'	System	09 Aug 2020 23:03:14
User entered 'None (0)'	System	09 Aug 2020 23:03:14

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:02:43', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '044af38d-2b62-4b66-844e-daa9621bf54a'	System	09 Aug 2020 23:03:14
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	09 Aug 2020 23:03:14



**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:02:47', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '044af38d-2b62-4b66-844e-daa9621bf54a'	System	09 Aug 2020 23:03:14
User entered 'None (0)'	System	09 Aug 2020 23:03:14

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:02:53', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '044af38d-2b62-4b66-844e-daa9621bf54a'	System	09 Aug 2020 23:03:14
User entered 'No (N)'	System	09 Aug 2020 23:03:14

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:03:12', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '044af38d-2b62-4b66-844e-daa9621bf54a'	System	09 Aug 2020 23:03:14
User entered '09 Aug 2020 18:03'	System	09 Aug 2020 23:03:14

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered 'Day 3'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:29:50', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c25676b9-5cd8-4f05-9de1-5e5d80ff242a'	System	10 Aug 2020 23:30:26
User entered 'None (0)'	System	10 Aug 2020 23:30:26

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:29:57', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c25676b9-5cd8-4f05-9de1-5e5d80ff242a'	System	10 Aug 2020 23:30:26
User entered 'No interference with activity (1)'	System	10 Aug 2020 23:30:26



**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:29:59', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c25676b9-5cd8-4f05-9de1-5e5d80ff242a'	System	10 Aug 2020 23:30:26
User entered 'None (0)'	System	10 Aug 2020 23:30:26

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:30:02', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c25676b9-5cd8-4f05-9de1-5e5d80ff242a'	System	10 Aug 2020 23:30:26
User entered 'None (0)'	System	10 Aug 2020 23:30:26

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:30:05', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c25676b9-5cd8-4f05-9de1-5e5d80ff242a'	System	10 Aug 2020 23:30:26
User entered 'None (0)'	System	10 Aug 2020 23:30:26

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:30:08', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c25676b9-5cd8-4f05-9de1-5e5d80ff242a'	System	10 Aug 2020 23:30:26
User entered 'None (0)'	System	10 Aug 2020 23:30:26

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:30:11', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c25676b9-5cd8-4f05-9de1-5e5d80ff242a'	System	10 Aug 2020 23:30:26
User entered 'No (N)'	System	10 Aug 2020 23:30:26

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:30:24', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c25676b9-5cd8-4f05-9de1-5e5d80ff242a'	System	10 Aug 2020 23:30:26
User entered '10 Aug 2020 18:30'	System	10 Aug 2020 23:30:26

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 23:39:00



**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered 'Day 4'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:58:16', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7afb8161-aa5d-464a-9b31-af5eea6e7a57'	System	11 Aug 2020 21:58:47
User entered 'None (0)'	System	11 Aug 2020 21:58:47

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:58:19', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7afb8161-aa5d-464a-9b31-af5eea6e7a57'	System	11 Aug 2020 21:58:47
User entered 'None (0)'	System	11 Aug 2020 21:58:47

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:58:21', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7afb8161-aa5d-464a-9b31-af5eea6e7a57'	System	11 Aug 2020 21:58:47
User entered 'None (0)'	System	11 Aug 2020 21:58:47

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:58:26', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7afb8161-aa5d-464a-9b31-af5eea6e7a57'	System	11 Aug 2020 21:58:47
User entered 'None (0)'	System	11 Aug 2020 21:58:47

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:58:30', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7afb8161-aa5d-464a-9b31-af5eea6e7a57'	System	11 Aug 2020 21:58:47
User entered 'None (0)'	System	11 Aug 2020 21:58:47

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:58:33', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7afb8161-aa5d-464a-9b31-af5eea6e7a57'	System	11 Aug 2020 21:58:47
User entered 'None (0)'	System	11 Aug 2020 21:58:47

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:58:36', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7afb8161-aa5d-464a-9b31-af5eea6e7a57'	System	11 Aug 2020 21:58:47
User entered 'No (N)'	System	11 Aug 2020 21:58:47



**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:58:45', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7afb8161-aa5d-464a-9b31-af5eea6e7a57'	System	11 Aug 2020 21:58:47
User entered '11 Aug 2020 16:58'	System	11 Aug 2020 21:58:47

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered 'Day 5'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:34:44', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2565f896-043d-4138-af35-9aaeb15b7e8a'	System	12 Aug 2020 22:35:20
User entered 'No interference with activity (1)'	System	12 Aug 2020 22:35:20

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:34:48', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2565f896-043d-4138-af35-9aaeb15b7e8a'	System	12 Aug 2020 22:35:20
User entered 'No interference with activity (1)'	System	12 Aug 2020 22:35:20

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:34:51', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2565f896-043d-4138-af35-9aaeb15b7e8a'	System	12 Aug 2020 22:35:20
User entered 'None (0)'	System	12 Aug 2020 22:35:20

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:34:56', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2565f896-043d-4138-af35-9aaeb15b7e8a'	System	12 Aug 2020 22:35:20
User entered 'None (0)'	System	12 Aug 2020 22:35:20



**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:35:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2565f896-043d-4138-af35-9aaeb15b7e8a'	System	12 Aug 2020 22:35:20
User entered 'None (0)'	System	12 Aug 2020 22:35:20

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:35:03', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2565f896-043d-4138-af35-9aaeb15b7e8a'	System	12 Aug 2020 22:35:20
User entered 'None (0)'	System	12 Aug 2020 22:35:20

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:35:06', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2565f896-043d-4138-af35-9aaeb15b7e8a'	System	12 Aug 2020 22:35:20
User entered 'No (N)'	System	12 Aug 2020 22:35:20

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:35:18', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2565f896-043d-4138-af35-9aaeb15b7e8a'	System	12 Aug 2020 22:35:20
User entered '12 Aug 2020 17:35'	System	12 Aug 2020 22:35:20

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered 'Day 6'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:24:40', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bc5e20d-59cb-4e03-927e-c8f9502983e1'	System	13 Aug 2020 22:25:13
User entered 'None (0)'	System	13 Aug 2020 22:25:13



**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:24:43', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bc5e20d-59cb-4e03-927e-c8f9502983e1'	System	13 Aug 2020 22:25:13
User entered 'None (0)'	System	13 Aug 2020 22:25:13

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:24:45', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bc5e20d-59cb-4e03-927e-c8f9502983e1'	System	13 Aug 2020 22:25:13
User entered 'None (0)'	System	13 Aug 2020 22:25:13

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:24:52', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bc5e20d-59cb-4e03-927e-c8f9502983e1'	System	13 Aug 2020 22:25:13
User entered 'None (0)'	System	13 Aug 2020 22:25:13

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:24:54', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bc5e20d-59cb-4e03-927e-c8f9502983e1'	System	13 Aug 2020 22:25:13
User entered 'None (0)'	System	13 Aug 2020 22:25:13

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:24:57', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bc5e20d-59cb-4e03-927e-c8f9502983e1'	System	13 Aug 2020 22:25:13
User entered 'None (0)'	System	13 Aug 2020 22:25:13

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:25:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bc5e20d-59cb-4e03-927e-c8f9502983e1'	System	13 Aug 2020 22:25:13
User entered 'No (N)'	System	13 Aug 2020 22:25:13

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:25:10', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bc5e20d-59cb-4e03-927e-c8f9502983e1' User entered '13 Aug 2020 17:25'	System	13 Aug 2020 22:25:13
	System	13 Aug 2020 22:25:13

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 23:39:00



**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered 'Day 7'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:51:37', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '79ffb750-f7b0-47be-b757-e2c982c7d6a6'	System	14 Aug 2020 21:52:13
User entered 'None (0)'	System	14 Aug 2020 21:52:13

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:51:40', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '79ffb750-f7b0-47be-b757-e2c982c7d6a6'	System	14 Aug 2020 21:52:13
User entered 'None (0)'	System	14 Aug 2020 21:52:13

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:51:42', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '79ffb750-f7b0-47be-b757-e2c982c7d6a6'	System	14 Aug 2020 21:52:13
User entered 'None (0)'	System	14 Aug 2020 21:52:13

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:51:45', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '79ffb750-f7b0-47be-b757-e2c982c7d6a6'	System	14 Aug 2020 21:52:13
User entered 'None (0)'	System	14 Aug 2020 21:52:13

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:51:51', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '79ffb750-f7b0-47be-b757-e2c982c7d6a6'	System	14 Aug 2020 21:52:13
User entered 'None (0)'	System	14 Aug 2020 21:52:13

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:51:53', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '79ffb750-f7b0-47be-b757-e2c982c7d6a6'	System	14 Aug 2020 21:52:13
User entered 'None (0)'	System	14 Aug 2020 21:52:13



**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:51:56', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '79ffb750-f7b0-47be-b757-e2c982c7d6a6'	System	14 Aug 2020 21:52:13
User entered 'No (N)'	System	14 Aug 2020 21:52:13

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:52:11', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '79ffb750-f7b0-47be-b757-e2c982c7d6a6'	System	14 Aug 2020 21:52:13
User entered '14 Aug 2020 16:52'	System	14 Aug 2020 21:52:13

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 22:24:14
User entered 'Day 8'	System	13 Aug 2020 22:24:14

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 10:55:50**

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-15T15:58:30', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '6902b270-db18-49c8-978c-17f2f06a1c46'	System	15 Aug 2020 20:58:41
User entered 'No (N)'	System	15 Aug 2020 20:58:41

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-15T15:58:36', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '6902b270-db18-49c8-978c-17f2f06a1c46'	System	15 Aug 2020 20:58:41
User entered '15 Aug 2020 15:58'	System	15 Aug 2020 20:58:41

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 22:24:14



**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 22:24:14

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 21:51:11
User entered 'Day 9'	System	14 Aug 2020 21:51:11

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 26 Nov 2020 10:55:50**

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-16T15:16:46', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'fda66b09-a872-4271-bfd8-d9f6fc962e79'	System	16 Aug 2020 20:16:55
User entered 'No (N)'	System	16 Aug 2020 20:16:55

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-16T15:16:53', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'fda66b09-a872-4271-bfd8-d9f6fc962e79'	System	16 Aug 2020 20:16:55
User entered '16 Aug 2020 15:16'	System	16 Aug 2020 20:16:55

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 21:51:11

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 21:51:11

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 20:58:29
User entered 'Day 10'	System	15 Aug 2020 20:58:29

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 26 Nov 2020 10:55:50**

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-17T14:18:32', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1a018f38-b3ef-4470-aa55-389ccda08358'	System	17 Aug 2020 19:18:36
User entered 'No (N)'	System	17 Aug 2020 19:18:36



**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-17T14:18:35', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1a018f38-b3ef-4470-aa55-389ccda08358'	System	17 Aug 2020 19:18:36
User entered '17 Aug 2020 14:18'	System	17 Aug 2020 19:18:36

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	15 Aug 2020 20:58:29

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	15 Aug 2020 20:58:29

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 20:16:46
User entered 'Day 11'	System	16 Aug 2020 20:16:46

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 26 Nov 2020 10:55:50

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-18T16:07:27', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '6a5efc9c-73b6-48db-ab9e-e567924458d0'	System	18 Aug 2020 21:07:35
User entered 'No (N)'	System	18 Aug 2020 21:07:35

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-18T16:07:31', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '6a5efc9c-73b6-48db-ab9e-e567924458d0'	System	18 Aug 2020 21:07:35
User entered '18 Aug 2020 16:07'	System	18 Aug 2020 21:07:35

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 20:16:46

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 20:16:46



**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 19:18:29
User entered 'Day 12'	System	17 Aug 2020 19:18:29

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 26 Nov 2020 10:55:50**

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-19T18:17:56', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8f018c8a-35f3-4f4d-ade4-da9ef5932dd9'	System	19 Aug 2020 23:18:05
User entered 'No (N)'	System	19 Aug 2020 23:18:05

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-19T18:17:59', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8f018c8a-35f3-4f4d-ade4-da9ef5932dd9'	System	19 Aug 2020 23:18:05
User entered '19 Aug 2020 18:17'	System	19 Aug 2020 23:18:05

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 19:18:29

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 19:18:29

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(13)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 21:07:24
User entered 'Day 13'	System	18 Aug 2020 21:07:24

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(13)**

**Generated On: 26 Nov 2020 10:55:50**

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-20T15:24:41', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '81aff379-b4ff-4911-b277-3ca1a603f6ed'	System	20 Aug 2020 20:24:47
User entered 'No (N)'	System	20 Aug 2020 20:24:47

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(13)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-20T15:24:45', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '81aff379-b4ff-4911-b277-3ca1a603f6ed'	System	20 Aug 2020 20:24:47
User entered '20 Aug 2020 15:24'	System	20 Aug 2020 20:24:47



**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(13)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 21:07:24

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(13)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 21:07:24

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(14)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 23:17:53
User entered 'Day 14'	System	19 Aug 2020 23:17:53

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 26 Nov 2020 10:55:50

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-21T23:59:55', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b698e6ec-016f-471e-b7b9-1d1d824a66b8'	System	22 Aug 2020 05:00:03
User entered 'No (N)'	System	22 Aug 2020 05:00:03

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(14)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-21T23:59:59', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b698e6ec-016f-471e-b7b9-1d1d824a66b8'	System	22 Aug 2020 05:00:03
User entered '21 Aug 2020 23:59'	System	22 Aug 2020 05:00:03

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(14)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 23:17:53

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(14)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 23:17:53

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(15)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 20:24:42
User entered 'Day 15'	System	20 Aug 2020 20:24:42



US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(15)

Generated On: 26 Nov 2020 10:55:50

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-22T17:12:43', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'ea367042-65cb-4433-b8e9-6606ead046f4'	System	22 Aug 2020 22:12:48
User entered 'No (N)'	System	22 Aug 2020 22:12:48

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(15)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-22T17:12:46', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'ea367042-65cb-4433-b8e9-6606ead046f4'	System	22 Aug 2020 22:12:48
User entered '22 Aug 2020 17:12'	System	22 Aug 2020 22:12:48

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(15)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 20:24:42

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(15)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 20:24:42

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(16)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	22 Aug 2020 04:59:53
User entered 'Day 16'	System	22 Aug 2020 04:59:53

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(16)

Generated On: 26 Nov 2020 10:55:50

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-23T16:07:06', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'df56accb-89e9-4d20-ab02-5943c308b6ee'	System	23 Aug 2020 21:07:16
User entered 'No (N)'	System	23 Aug 2020 21:07:16

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(16)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-23T16:07:12', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'df56accb-89e9-4d20-ab02-5943c308b6ee' User entered '23 Aug 2020 16:07'	System	23 Aug 2020 21:07:16
	System	23 Aug 2020 21:07:16

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(16)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 04:59:53



**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(16)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 04:59:53

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(17)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	22 Aug 2020 22:12:40
User entered 'Day 17'	System	22 Aug 2020 22:12:40

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(17)**

**Generated On: 26 Nov 2020 10:55:50**

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-24T14:54:37', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '3e281df7-3192-4233-b1f8-59bc513f1de1'	System	24 Aug 2020 19:54:43
User entered 'No (N)'	System	24 Aug 2020 19:54:43

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(17)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-24T14:54:41', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '3e281df7-3192-4233-b1f8-59bc513f1de1'	System	24 Aug 2020 19:54:43
User entered '24 Aug 2020 14:54'	System	24 Aug 2020 19:54:43

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(17)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 22:12:40

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(17)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 22:12:40

**US3292103**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	19 Aug 2020 02:24:20

**US3292103**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Aug 2020'	Dawn Killian (b) (4) (b) (4)	19 Aug 2020 02:24:20



**US3292103**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Dawn Killian (b) (4) (b) (4)	19 Aug 2020 02:24:20

**US3292103**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Dawn Killian (b) (4) (b) (4)	19 Aug 2020 02:24:20

**US3292103**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	19 Aug 2020 02:24:09

**US3292103**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Aug 2020 02:24:09

**US3292103**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	24 Aug 2020 19:51:09

**US3292103**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Kristy Trevino (b) (4) (b) (4)	24 Aug 2020 19:51:09

**US3292103**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kristy Trevino (b) (4) (b) (4)	24 Aug 2020 19:51:09

**US3292103**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Kristy Trevino (b) (4) (b) (4)	24 Aug 2020 19:51:09



**US3292103**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	24 Aug 2020 19:53:35

**US3292103**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Aug 2020 19:53:35

**US3292103**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	30 Aug 2020 02:41:25

**US3292103**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	Kristy Trevino (b) (4) (b) (4)	30 Aug 2020 02:41:25

**US3292103**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kristy Trevino (b) (4) (b) (4)	30 Aug 2020 02:41:25

**US3292103**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Kristy Trevino (b) (4) (b) (4)	30 Aug 2020 02:41:25

**US3292103**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	30 Aug 2020 02:41:51

**US3292103**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Aug 2020 02:41:51



**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:55:50**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:14:02

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:55:50**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '5 Sep 2020'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:14:02

US3292103

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:50

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:14:02

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:55:50**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	05 Sep 2020 19:14:02

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:15:12

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:50

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:15:12

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '5 Sep 2020'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:15:12

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:50**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User entered '12:33'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:15:12



**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '5 Sep 2020 12:33'	System	05 Sep 2020 19:15:12

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:50

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.4' C	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:15:12

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:50

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:15:12

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:50**

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:15:12

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '79'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:15:12

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Sep 2020 19:15:12

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:15:12

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Sep 2020 19:15:12



US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '137'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:15:12

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Sep 2020 19:15:12

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '74'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:15:12

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Sep 2020 19:15:12

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:55:50**

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:16:04

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:50

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:16:04

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:55:50**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '5 Sep 2020'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:16:04

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:55:50**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User entered '13:51'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:16:04



**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:55:50**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '5 Sep 2020 13:51'	System	05 Sep 2020 19:16:04

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:50

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.7' C	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:16:04

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:50

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:16:04

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:55:50**

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:16:04

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:55:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '75'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:16:04

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:55:50**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Sep 2020 19:16:04

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:16:04

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:55:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Sep 2020 19:16:04



US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '127'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:16:04

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:55:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Sep 2020 19:16:04

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '76'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:16:04

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:55:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Sep 2020 19:16:04

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 10:55:50**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:16:18

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 10:55:50**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User entered '5 Sep 2020'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:16:18

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:55:50**

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Sep 2020 18:30:38

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:55:50**

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Sep 2020 18:30:38



US3292103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:50

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)	05 Sep 2020 18:30:38

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:55:50**

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	05 Sep 2020 18:30:38

US3292103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '5 Sep 2020'	(b) (4), (b) (6)	05 Sep 2020 18:30:38

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:55:50**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '13:21'	(b) (4), (b) (6)	05 Sep 2020 18:30:38

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:55:50**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '5 Sep 2020 13:21'	System	05 Sep 2020 18:30:38

US3292103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:50

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	05 Sep 2020 18:30:38

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:55:50**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:55:50**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	05 Sep 2020 18:30:38



US3292103

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:50

Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:16:37

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:55:50**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '5 Sep 2020'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:16:37

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:55:50**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:42'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:16:37

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:55:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '5 Sep 2020 12:42'	System	05 Sep 2020 19:16:37

US3292103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:55:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '5 Sep 2020'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:16:54

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:16:54

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:16:54

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:55:50**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
User entered '12:48'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:16:54



**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '5 Sep 2020 12:48'	System	05 Sep 2020 19:16:54

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:55:50**

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:16:54

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:55:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:16:54

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:55:50**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
User entered empty.	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:16:54

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:55:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Sep 2020 19:16:54

US3292103

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	05 Sep 2020 19:17:06

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 19:17:06

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Sep 2020 18:30:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Sep 2020 18:30:38



**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:54:21', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8b54c32c-987b-4253-b772-e41e08e71962'	System	05 Sep 2020 18:54:40
User entered 'Yes (Y)'	System	05 Sep 2020 18:54:40

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:54:28', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8b54c32c-987b-4253-b772-e41e08e71962'	System	05 Sep 2020 18:54:40
User entered '98.0'	System	05 Sep 2020 18:54:40

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

**Was any MEDICATION TAKEN today for pain or fever?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:54:31', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8b54c32c-987b-4253-b772-e41e08e71962'	System	05 Sep 2020 18:54:40
User entered 'No (N)'	System	05 Sep 2020 18:54:40

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:54:35', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8b54c32c-987b-4253-b772-e41e08e71962'	System	05 Sep 2020 18:54:40
User entered '05 Sep 2020 13:54'	System	05 Sep 2020 18:54:40

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 13:41'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 16:11'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Sep 2020 18:30:38
User entered 'Day 1, after vaccination (at home)'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:33:34', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '043294c0-c30e-4817-aa53-f758e0b165c6'	System	06 Sep 2020 00:33:52
User entered 'Yes (Y)'	System	06 Sep 2020 00:33:52



**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:33:41', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '043294c0-c30e-4817-aa53-f758e0b165c6'	System	06 Sep 2020 00:33:52
User entered '97.7'	System	06 Sep 2020 00:33:52

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

**Was any MEDICATION TAKEN today for pain or fever?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:33:44', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '043294c0-c30e-4817-aa53-f758e0b165c6'	System	06 Sep 2020 00:33:52
User entered 'No (N)'	System	06 Sep 2020 00:33:52

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:33:50', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '043294c0-c30e-4817-aa53-f758e0b165c6'	System	06 Sep 2020 00:33:52
User entered '05 Sep 2020 19:33'	System	06 Sep 2020 00:33:52

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 17:06'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Sep 2020 18:30:38
User entered 'Day 2'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:30:55', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'bb6fb165-1836-4676-98d5-40cc22437c2a'	System	06 Sep 2020 23:31:13
User entered 'Yes (Y)'	System	06 Sep 2020 23:31:13

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:31:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'bb6fb165-1836-4676-98d5-40cc22437c2a'	System	06 Sep 2020 23:31:13
User entered '98.2'	System	06 Sep 2020 23:31:13



US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:55:50

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:31:03', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'bb6fb165-1836-4676-98d5-40cc22437c2a'	System	06 Sep 2020 23:31:13
User entered 'No (N)'	System	06 Sep 2020 23:31:13

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:31:07', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'bb6fb165-1836-4676-98d5-40cc22437c2a'	System	06 Sep 2020 23:31:13
User entered '06 Sep 2020 18:31'	System	06 Sep 2020 23:31:13

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Sep 2020 18:30:38
User entered 'Day 3'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:03:38', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '78826bb7-1f89-4a73-9767-9a7472aaab16'	System	07 Sep 2020 22:03:53
User entered 'Yes (Y)'	System	07 Sep 2020 22:03:53

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:03:43', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '78826bb7-1f89-4a73-9767-9a7472aaab16'	System	07 Sep 2020 22:03:53
User entered '98.2'	System	07 Sep 2020 22:03:53

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

**Was any MEDICATION TAKEN today for pain or fever?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:03:46', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '78826bb7-1f89-4a73-9767-9a7472aaab16'	System	07 Sep 2020 22:03:53
User entered 'No (N)'	System	07 Sep 2020 22:03:53



**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:03:50', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '78826bb7-1f89-4a73-9767-9a7472aaab16'	System	07 Sep 2020 22:03:53
User entered '07 Sep 2020 17:03'	System	07 Sep 2020 22:03:53

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Sep 2020 18:30:38
User entered 'Day 4'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:13:59', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'e07d04b9-0f09-4540-916f-063ead6c981a'	System	09 Sep 2020 00:14:14
User entered 'Yes (Y)'	System	09 Sep 2020 00:14:14

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:03', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'e07d04b9-0f09-4540-916f-063ead6c981a'	System	09 Sep 2020 00:14:14
User entered '98.0'	System	09 Sep 2020 00:14:14

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:55:50

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:06', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'e07d04b9-0f09-4540-916f-063ead6c981a'	System	09 Sep 2020 00:14:14
User entered 'No (N)'	System	09 Sep 2020 00:14:14

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:11', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'e07d04b9-0f09-4540-916f-063ead6c981a'	System	09 Sep 2020 00:14:14
User entered '08 Sep 2020 19:14'	System	09 Sep 2020 00:14:14



**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Sep 2020 18:30:38
User entered 'Day 5'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:14:36', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a6256e47-8bf6-4fbf-92ab-8a510a66b033'	System	09 Sep 2020 22:14:51
User entered 'Yes (Y)'	System	09 Sep 2020 22:14:51

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:14:41', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a6256e47-8bf6-4fbf-92ab-8a510a66b033'	System	09 Sep 2020 22:14:51
User entered '98.0'	System	09 Sep 2020 22:14:51

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:55:50

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:14:44', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a6256e47-8bf6-4fbf-92ab-8a510a66b033'	System	09 Sep 2020 22:14:51
User entered 'No (N)'	System	09 Sep 2020 22:14:51

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:14:48', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a6256e47-8bf6-4fbf-92ab-8a510a66b033'	System	09 Sep 2020 22:14:51
User entered '09 Sep 2020 17:14'	System	09 Sep 2020 22:14:51

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	05 Sep 2020 18:30:38



**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Sep 2020 18:30:38
User entered 'Day 6'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:33:40', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'cf552e68-a4c6-4973-b946-6520b7d19116'	System	10 Sep 2020 23:33:55
User entered 'Yes (Y)'	System	10 Sep 2020 23:33:55

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:33:44', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'cf552e68-a4c6-4973-b946-6520b7d19116'	System	10 Sep 2020 23:33:55
User entered '98.0'	System	10 Sep 2020 23:33:55

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

**Was any MEDICATION TAKEN today for pain or fever?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:33:50', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'cf552e68-a4c6-4973-b946-6520b7d19116'	System	10 Sep 2020 23:33:55
User entered 'No (N)'	System	10 Sep 2020 23:33:55

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:33:53', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'cf552e68-a4c6-4973-b946-6520b7d19116'	System	10 Sep 2020 23:33:55
User entered '10 Sep 2020 18:33'	System	10 Sep 2020 23:33:55

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	05 Sep 2020 18:30:38



**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Sep 2020 18:30:38
User entered 'Day 7'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:32:07', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '3d13d264-e06b-4285-b0fa-2011a351486e'	System	11 Sep 2020 22:32:54
User entered 'Yes (Y)'	System	11 Sep 2020 22:32:54

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:32:12', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '3d13d264-e06b-4285-b0fa-2011a351486e'	System	11 Sep 2020 22:32:54
User entered '98.0'	System	11 Sep 2020 22:32:54

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

**Was any MEDICATION TAKEN today for pain or fever?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:32:16', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '3d13d264-e06b-4285-b0fa-2011a351486e'	System	11 Sep 2020 22:32:54
User entered 'No (N)'	System	11 Sep 2020 22:32:54

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:32:21', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '3d13d264-e06b-4285-b0fa-2011a351486e'	System	11 Sep 2020 22:32:54
User entered '11 Sep 2020 17:32'	System	11 Sep 2020 22:32:54

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Sep 2020 18:30:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Sep 2020 18:30:38



**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

[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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:54:41', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '933bae30-ee5c-4b4f-8d90-b1c648e30b8d' User entered 'None (1)'	System	05 Sep 2020 18:54:58
	System	05 Sep 2020 18:54:58

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:54:45', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '933bae30-ee5c-4b4f-8d90-b1c648e30b8d'	System	05 Sep 2020 18:54:58
User entered 'No (N)'	System	05 Sep 2020 18:54:58

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:54:48', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '933bae30-ee5c-4b4f-8d90-b1c648e30b8d'	System	05 Sep 2020 18:54:58
User entered 'No (N)'	System	05 Sep 2020 18:54:58

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

[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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:54:53', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '933bae30-ee5c-4b4f-8d90-b1c648e30b8d' User entered 'None (1)'	System	05 Sep 2020 18:54:58
	System	05 Sep 2020 18:54:58

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:54:56', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '933bae30-ee5c-4b4f-8d90-b1c648e30b8d' User entered '05 Sep 2020 13:54'	System	05 Sep 2020 18:54:58
	System	05 Sep 2020 18:54:58

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 13:41'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 16:11'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Sep 2020 18:30:38
User entered 'Day 1, after vaccination (at home)'	System	05 Sep 2020 18:30:38



**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

[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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:33:56', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7128b11b-0367-4103-b957-1c3f6a830804'	System	06 Sep 2020 00:34:20
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 00:34:20

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:34:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7128b11b-0367-4103-b957-1c3f6a830804'	System	06 Sep 2020 00:34:20
User entered 'No (N)'	System	06 Sep 2020 00:34:20

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:34:09', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7128b11b-0367-4103-b957-1c3f6a830804'	System	06 Sep 2020 00:34:20
User entered 'No (N)'	System	06 Sep 2020 00:34:20

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:55:50

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:34:15', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7128b11b-0367-4103-b957-1c3f6a830804'	System	06 Sep 2020 00:34:20
User entered 'None (1)'	System	06 Sep 2020 00:34:20

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:34:17', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7128b11b-0367-4103-b957-1c3f6a830804'	System	06 Sep 2020 00:34:20
User entered '05 Sep 2020 19:34'	System	06 Sep 2020 00:34:20

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 17:06'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Sep 2020 18:30:38
User entered 'Day 2'	System	05 Sep 2020 18:30:38



**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

[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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:31:14', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c51cd2e6-6a88-4ebc-a040-cb7291fb08dd'	System	06 Sep 2020 23:32:06
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 23:32:06

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:31:18', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c51cd2e6-6a88-4ebc-a040-cb7291fb08dd'	System	06 Sep 2020 23:32:06
User entered 'No (N)'	System	06 Sep 2020 23:32:06

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:31:45', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c51cd2e6-6a88-4ebc-a040-cb7291fb08dd'	System	06 Sep 2020 23:32:06
User entered 'No (N)'	System	06 Sep 2020 23:32:06

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:55:50

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:31:50', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c51cd2e6-6a88-4ebc-a040-cb7291fb08dd'	System	06 Sep 2020 23:32:06
User entered 'None (1)'	System	06 Sep 2020 23:32:06

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:32:02', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c51cd2e6-6a88-4ebc-a040-cb7291fb08dd'	System	06 Sep 2020 23:32:06
User entered '06 Sep 2020 18:32'	System	06 Sep 2020 23:32:06

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Sep 2020 18:30:38
User entered 'Day 3'	System	05 Sep 2020 18:30:38



**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

[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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:03:57', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b908ef6b-e4ac-4210-8950-c1af38aeb4ea'	System	07 Sep 2020 22:04:15
User entered 'Does not interfere with activity (2)'	System	07 Sep 2020 22:04:15

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:04:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b908ef6b-e4ac-4210-8950-c1af38aeb4ea'	System	07 Sep 2020 22:04:15
User entered 'No (N)'	System	07 Sep 2020 22:04:15

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:04:07', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b908ef6b-e4ac-4210-8950-c1af38aeb4ea'	System	07 Sep 2020 22:04:15
User entered 'No (N)'	System	07 Sep 2020 22:04:15

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:55:50

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:04:10', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b908ef6b-e4ac-4210-8950-c1af38aeb4ea'	System	07 Sep 2020 22:04:15
User entered 'None (1)'	System	07 Sep 2020 22:04:15

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:04:13', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b908ef6b-e4ac-4210-8950-c1af38aeb4ea'	System	07 Sep 2020 22:04:15
User entered '07 Sep 2020 17:04'	System	07 Sep 2020 22:04:15

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Sep 2020 18:30:38
User entered 'Day 4'	System	05 Sep 2020 18:30:38



**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

[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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:19', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '044f52ee-df5e-41d6-99a7-1e40649f66af'	System	09 Sep 2020 00:14:33
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 00:14:33

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:22', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '044f52ee-df5e-41d6-99a7-1e40649f66af'	System	09 Sep 2020 00:14:33
User entered 'No (N)'	System	09 Sep 2020 00:14:33

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:25', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '044f52ee-df5e-41d6-99a7-1e40649f66af'	System	09 Sep 2020 00:14:33
User entered 'No (N)'	System	09 Sep 2020 00:14:33

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:55:50

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:27', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '044f52ee-df5e-41d6-99a7-1e40649f66af' User entered 'None (1)'	System	09 Sep 2020 00:14:33
	System	09 Sep 2020 00:14:33

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:30', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '044f52ee-df5e-41d6-99a7-1e40649f66af' User entered '08 Sep 2020 19:14'	System	09 Sep 2020 00:14:33

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Sep 2020 18:30:38
User entered 'Day 5'	System	05 Sep 2020 18:30:38



**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

[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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:14:57', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '3bb5a348-e842-41ab-8224-80ef6059149f'	System	09 Sep 2020 22:15:17
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 22:15:17

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:15:01', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '3bb5a348-e842-41ab-8224-80ef6059149f'	System	09 Sep 2020 22:15:17
User entered 'No (N)'	System	09 Sep 2020 22:15:17

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:15:06', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '3bb5a348-e842-41ab-8224-80ef6059149f'	System	09 Sep 2020 22:15:17
User entered 'No (N)'	System	09 Sep 2020 22:15:17

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:55:50

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:15:09', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '3bb5a348-e842-41ab-8224-80ef6059149f' User entered 'None (1)'	System	09 Sep 2020 22:15:17
	System	09 Sep 2020 22:15:17

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:15:12', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '3bb5a348-e842-41ab-8224-80ef6059149f'	System	09 Sep 2020 22:15:17
User entered '09 Sep 2020 17:15'	System	09 Sep 2020 22:15:17

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Sep 2020 18:30:38
User entered 'Day 6'	System	05 Sep 2020 18:30:38



**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

[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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:34:03', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '60305789-a5b1-4f7d-b4fa-3d363e7e70e7'	System	10 Sep 2020 23:34:21
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 23:34:21

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:34:06', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '60305789-a5b1-4f7d-b4fa-3d363e7e70e7'	System	10 Sep 2020 23:34:21
User entered 'No (N)'	System	10 Sep 2020 23:34:21

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:34:08', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '60305789-a5b1-4f7d-b4fa-3d363e7e70e7'	System	10 Sep 2020 23:34:21
User entered 'No (N)'	System	10 Sep 2020 23:34:21

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:55:50

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:34:12', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '60305789-a5b1-4f7d-b4fa-3d363e7e70e7'	System	10 Sep 2020 23:34:21
User entered 'None (1)'	System	10 Sep 2020 23:34:21

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:34:19', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '60305789-a5b1-4f7d-b4fa-3d363e7e70e7'	System	10 Sep 2020 23:34:21
User entered '10 Sep 2020 18:34'	System	10 Sep 2020 23:34:21

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Sep 2020 18:30:38
User entered 'Day 7'	System	05 Sep 2020 18:30:38



**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

[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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:32:28', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b8d1b372-9bcf-4bf8-b122-8617cdd3d5ee'	System	11 Sep 2020 22:33:00
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 22:33:00

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:32:31', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b8d1b372-9bcf-4bf8-b122-8617cdd3d5ee'	System	11 Sep 2020 22:33:00
User entered 'No (N)'	System	11 Sep 2020 22:33:00

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:32:33', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b8d1b372-9bcf-4bf8-b122-8617cdd3d5ee'	System	11 Sep 2020 22:33:00
User entered 'No (N)'	System	11 Sep 2020 22:33:00

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:55:50

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:32:36', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b8d1b372-9bcf-4bf8-b122-8617cdd3d5ee'	System	11 Sep 2020 22:33:00
User entered 'None (1)'	System	11 Sep 2020 22:33:00

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:32:42', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b8d1b372-9bcf-4bf8-b122-8617cdd3d5ee'	System	11 Sep 2020 22:33:00
User entered '11 Sep 2020 17:32'	System	11 Sep 2020 22:33:00

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Sep 2020 18:30:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Sep 2020 18:30:38



**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:55:02', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8d24bd89-8d08-4117-a5e3-27c8e273ce01'	System	05 Sep 2020 18:55:29
User entered 'None (0)'	System	05 Sep 2020 18:55:29

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:55:05', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8d24bd89-8d08-4117-a5e3-27c8e273ce01'	System	05 Sep 2020 18:55:29
User entered 'None (0)'	System	05 Sep 2020 18:55:29

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:55:08', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8d24bd89-8d08-4117-a5e3-27c8e273ce01'	System	05 Sep 2020 18:55:29
User entered 'None (0)'	System	05 Sep 2020 18:55:29

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:55:10', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8d24bd89-8d08-4117-a5e3-27c8e273ce01'	System	05 Sep 2020 18:55:29
User entered 'None (0)'	System	05 Sep 2020 18:55:29

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:55:13', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8d24bd89-8d08-4117-a5e3-27c8e273ce01'	System	05 Sep 2020 18:55:29
User entered 'None (0)'	System	05 Sep 2020 18:55:29

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:55:15', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8d24bd89-8d08-4117-a5e3-27c8e273ce01'	System	05 Sep 2020 18:55:29
User entered 'None (0)'	System	05 Sep 2020 18:55:29

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:55:23', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8d24bd89-8d08-4117-a5e3-27c8e273ce01'	System	05 Sep 2020 18:55:29
User entered 'No (N)'	System	05 Sep 2020 18:55:29

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:55:26', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8d24bd89-8d08-4117-a5e3-27c8e273ce01'	System	05 Sep 2020 18:55:29
User entered '05 Sep 2020 13:55'	System	05 Sep 2020 18:55:29



**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 13:41'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 16:11'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Sep 2020 18:30:38
User entered 'Day 1, after vaccination (at home)'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:34:24', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd8ede341-97a7-419f-bc78-e1eb440c06d5'	System	06 Sep 2020 00:34:57
User entered 'None (0)'	System	06 Sep 2020 00:34:57

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:34:30', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd8ede341-97a7-419f-bc78-e1eb440c06d5'	System	06 Sep 2020 00:34:57
User entered 'No interference with activity (1)'	System	06 Sep 2020 00:34:57

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:34:32', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd8ede341-97a7-419f-bc78-e1eb440c06d5'	System	06 Sep 2020 00:34:57
User entered 'None (0)'	System	06 Sep 2020 00:34:57

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:34:35', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd8ede341-97a7-419f-bc78-e1eb440c06d5'	System	06 Sep 2020 00:34:57
User entered 'None (0)'	System	06 Sep 2020 00:34:57

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:34:40', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd8ede341-97a7-419f-bc78-e1eb440c06d5'	System	06 Sep 2020 00:34:57
User entered 'None (0)'	System	06 Sep 2020 00:34:57



**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:34:43', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd8ede341-97a7-419f-bc78-e1eb440c06d5'	System	06 Sep 2020 00:34:57
User entered 'None (0)'	System	06 Sep 2020 00:34:57

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:34:46', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd8ede341-97a7-419f-bc78-e1eb440c06d5'	System	06 Sep 2020 00:34:57
User entered 'No (N)'	System	06 Sep 2020 00:34:57

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:34:53', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd8ede341-97a7-419f-bc78-e1eb440c06d5'	System	06 Sep 2020 00:34:57
User entered '05 Sep 2020 19:34'	System	06 Sep 2020 00:34:57

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 17:06'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Sep 2020 18:30:38
User entered 'Day 2'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:32:08', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1d78fbbf-0b41-41b4-aef6-bfd6c23f5a24'	System	06 Sep 2020 23:32:51
User entered 'No interference with activity (1)'	System	06 Sep 2020 23:32:51

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:32:11', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1d78fbbf-0b41-41b4-aef6-bfd6c23f5a24'	System	06 Sep 2020 23:32:51
User entered 'Some interference with activity (2)'	System	06 Sep 2020 23:32:51



**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:32:15', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1d78fbbf-0b41-41b4-aef6-bfd6c23f5a24'	System	06 Sep 2020 23:32:51
User entered 'None (0)'	System	06 Sep 2020 23:32:51

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:32:18', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1d78fbbf-0b41-41b4-aef6-bfd6c23f5a24'	System	06 Sep 2020 23:32:51
User entered 'None (0)'	System	06 Sep 2020 23:32:51

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:32:23', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1d78fbbf-0b41-41b4-aef6-bfd6c23f5a24'	System	06 Sep 2020 23:32:51
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	06 Sep 2020 23:32:51

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:32:26', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1d78fbbf-0b41-41b4-aef6-bfd6c23f5a24'	System	06 Sep 2020 23:32:51
User entered 'None (0)'	System	06 Sep 2020 23:32:51

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:32:29', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1d78fbbf-0b41-41b4-aef6-bfd6c23f5a24'	System	06 Sep 2020 23:32:51
User entered 'No (N)'	System	06 Sep 2020 23:32:51

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:32:48', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1d78fbbf-0b41-41b4-aef6-bfd6c23f5a24'	System	06 Sep 2020 23:32:51
User entered '06 Sep 2020 18:32'	System	06 Sep 2020 23:32:51

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 18:30:38



**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Sep 2020 18:30:38
User entered 'Day 3'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:04:17', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'da6e53cd-dbb1-4dbe-aaa5-0c93ea631e60'	System	07 Sep 2020 22:04:38
User entered 'None (0)'	System	07 Sep 2020 22:04:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:04:20', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'da6e53cd-dbb1-4dbe-aaa5-0c93ea631e60'	System	07 Sep 2020 22:04:38
User entered 'None (0)'	System	07 Sep 2020 22:04:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:04:22', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'da6e53cd-dbb1-4dbe-aaa5-0c93ea631e60'	System	07 Sep 2020 22:04:38
User entered 'None (0)'	System	07 Sep 2020 22:04:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:04:26', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'da6e53cd-dbb1-4dbe-aaa5-0c93ea631e60'	System	07 Sep 2020 22:04:38
User entered 'None (0)'	System	07 Sep 2020 22:04:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:04:28', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'da6e53cd-dbb1-4dbe-aaa5-0c93ea631e60'	System	07 Sep 2020 22:04:38
User entered 'None (0)'	System	07 Sep 2020 22:04:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:04:31', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'da6e53cd-dbb1-4dbe-aaa5-0c93ea631e60'	System	07 Sep 2020 22:04:38
User entered 'None (0)'	System	07 Sep 2020 22:04:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:04:34', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'da6e53cd-dbb1-4dbe-aaa5-0c93ea631e60'	System	07 Sep 2020 22:04:38
User entered 'No (N)'	System	07 Sep 2020 22:04:38



**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:04:36', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'da6e53cd-dbb1-4dbe-aaa5-0c93ea631e60'	System	07 Sep 2020 22:04:38
User entered '07 Sep 2020 17:04'	System	07 Sep 2020 22:04:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Sep 2020 18:30:38
User entered 'Day 4'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:36', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a7207fae-f943-4692-adaa-8cdda3edabe2'	System	09 Sep 2020 00:14:57
User entered 'None (0)'	System	09 Sep 2020 00:14:57

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:39', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a7207fae-f943-4692-adaa-8cdda3edabe2'	System	09 Sep 2020 00:14:57
User entered 'None (0)'	System	09 Sep 2020 00:14:57

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:41', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a7207fae-f943-4692-adaa-8cdda3edabe2'	System	09 Sep 2020 00:14:57
User entered 'None (0)'	System	09 Sep 2020 00:14:57

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:43', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a7207fae-f943-4692-adaa-8cdda3edabe2'	System	09 Sep 2020 00:14:57
User entered 'None (0)'	System	09 Sep 2020 00:14:57



**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:48', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a7207fae-f943-4692-adaa-8cdda3edabe2'	System	09 Sep 2020 00:14:57
User entered 'None (0)'	System	09 Sep 2020 00:14:57

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:50', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a7207fae-f943-4692-adaa-8cdda3edabe2'	System	09 Sep 2020 00:14:57
User entered 'None (0)'	System	09 Sep 2020 00:14:57

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:53', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a7207fae-f943-4692-adaa-8cdda3edabe2'	System	09 Sep 2020 00:14:57
User entered 'No (N)'	System	09 Sep 2020 00:14:57

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:55', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a7207fae-f943-4692-adaa-8cdda3edabe2'	System	09 Sep 2020 00:14:57
User entered '08 Sep 2020 19:14'	System	09 Sep 2020 00:14:57

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Sep 2020 18:30:38
User entered 'Day 5'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:15:16', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1745ff90-66ef-4393-b4aa-a12a7616f465'	System	09 Sep 2020 22:15:59
User entered 'None (0)'	System	09 Sep 2020 22:15:59



**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:15:19', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1745ff90-66ef-4393-b4aa-a12a7616f465'	System	09 Sep 2020 22:15:59
User entered 'None (0)'	System	09 Sep 2020 22:15:59

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:15:25', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1745ff90-66ef-4393-b4aa-a12a7616f465'	System	09 Sep 2020 22:15:59
User entered 'None (0)'	System	09 Sep 2020 22:15:59

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:15:28', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1745ff90-66ef-4393-b4aa-a12a7616f465'	System	09 Sep 2020 22:15:59
User entered 'None (0)'	System	09 Sep 2020 22:15:59

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:15:35', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1745ff90-66ef-4393-b4aa-a12a7616f465'	System	09 Sep 2020 22:15:59
User entered 'None (0)'	System	09 Sep 2020 22:15:59

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:15:40', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1745ff90-66ef-4393-b4aa-a12a7616f465'	System	09 Sep 2020 22:15:59
User entered 'None (0)'	System	09 Sep 2020 22:15:59

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:15:43', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1745ff90-66ef-4393-b4aa-a12a7616f465'	System	09 Sep 2020 22:15:59
User entered 'No (N)'	System	09 Sep 2020 22:15:59

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:15:58', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1745ff90-66ef-4393-b4aa-a12a7616f465'	System	09 Sep 2020 22:15:59
User entered '09 Sep 2020 17:15'	System	09 Sep 2020 22:15:59

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	05 Sep 2020 18:30:38



**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Sep 2020 18:30:38
User entered 'Day 6'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:34:24', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '14eb93aa-8595-475c-bc9e-2e9c169fb416'	System	10 Sep 2020 23:34:49
User entered 'None (0)'	System	10 Sep 2020 23:34:49

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:34:26', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '14eb93aa-8595-475c-bc9e-2e9c169fb416'	System	10 Sep 2020 23:34:49
User entered 'None (0)'	System	10 Sep 2020 23:34:49

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:34:28', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '14eb93aa-8595-475c-bc9e-2e9c169fb416'	System	10 Sep 2020 23:34:49
User entered 'None (0)'	System	10 Sep 2020 23:34:49

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:34:31', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '14eb93aa-8595-475c-bc9e-2e9c169fb416'	System	10 Sep 2020 23:34:49
User entered 'None (0)'	System	10 Sep 2020 23:34:49

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:34:33', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '14eb93aa-8595-475c-bc9e-2e9c169fb416'	System	10 Sep 2020 23:34:49
User entered 'None (0)'	System	10 Sep 2020 23:34:49

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:34:35', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '14eb93aa-8595-475c-bc9e-2e9c169fb416'	System	10 Sep 2020 23:34:49
User entered 'None (0)'	System	10 Sep 2020 23:34:49



**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:34:38', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '14eb93aa-8595-475c-bc9e-2e9c169fb416'	System	10 Sep 2020 23:34:49
User entered 'No (N)'	System	10 Sep 2020 23:34:49

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:34:45', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '14eb93aa-8595-475c-bc9e-2e9c169fb416'	System	10 Sep 2020 23:34:49
User entered '10 Sep 2020 18:34'	System	10 Sep 2020 23:34:49

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	05 Sep 2020 18:30:38
User entered 'Day 7'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:32:46', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2c7ec7ea-df99-45d3-a8f0-b3c2a3178412'	System	11 Sep 2020 22:33:18
User entered 'None (0)'	System	11 Sep 2020 22:33:18

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:32:48', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2c7ec7ea-df99-45d3-a8f0-b3c2a3178412'	System	11 Sep 2020 22:33:18
User entered 'None (0)'	System	11 Sep 2020 22:33:18

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:32:50', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2c7ec7ea-df99-45d3-a8f0-b3c2a3178412'	System	11 Sep 2020 22:33:18
User entered 'None (0)'	System	11 Sep 2020 22:33:18



**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:32:53', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2c7ec7ea-df99-45d3-a8f0-b3c2a3178412'	System	11 Sep 2020 22:33:18
User entered 'None (0)'	System	11 Sep 2020 22:33:18

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:32:55', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2c7ec7ea-df99-45d3-a8f0-b3c2a3178412'	System	11 Sep 2020 22:33:18
User entered 'None (0)'	System	11 Sep 2020 22:33:18

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:32:58', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2c7ec7ea-df99-45d3-a8f0-b3c2a3178412'	System	11 Sep 2020 22:33:18
User entered 'None (0)'	System	11 Sep 2020 22:33:18

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:33:01', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2c7ec7ea-df99-45d3-a8f0-b3c2a3178412'	System	11 Sep 2020 22:33:18
User entered 'No (N)'	System	11 Sep 2020 22:33:18

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:33:10', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2c7ec7ea-df99-45d3-a8f0-b3c2a3178412'	System	11 Sep 2020 22:33:18
User entered '11 Sep 2020 17:33'	System	11 Sep 2020 22:33:18

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	05 Sep 2020 18:30:38

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Pain\_Day(8)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 23:34:21
User entered 'Day 8'	System	10 Sep 2020 23:34:21



**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Pain\_Day(8)**

**Generated On: 26 Nov 2020 10:55:50**

[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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-12T12:21:36', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '58438b66-77cf-4ac7-a750-d5efc409ad05'	System	12 Sep 2020 17:21:42
User entered 'None (1)'	System	12 Sep 2020 17:21:42

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Pain\_Day(8)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-12T12:21:41', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '58438b66-77cf-4ac7-a750-d5efc409ad05'	System	12 Sep 2020 17:21:42
User entered '12 Sep 2020 12:21'	System	12 Sep 2020 17:21:42

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Pain\_Day(8)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 23:34:21

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Pain\_Day(8)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 23:34:21

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 23:34:21
User entered 'Day 8'	System	10 Sep 2020 23:34:21

US3292103

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 26 Nov 2020 10:55:50

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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-12T12:21:45', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '375cb104-63b5-4243-b894-dead74d4461e'	System	12 Sep 2020 17:21:52
User entered 'No (N)'	System	12 Sep 2020 17:21:52

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-12T12:21:49', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '375cb104-63b5-4243-b894-dead74d4461e'	System	12 Sep 2020 17:21:52
User entered '12 Sep 2020 12:21'	System	12 Sep 2020 17:21:52

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 23:34:21



**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 10:55:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 23:34:21

**US3292103**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	14 Sep 2020 18:35:49

**US3292103**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Kristy Trevino (b) (4) (b) (4)	14 Sep 2020 18:35:49

**US3292103**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kristy Trevino (b) (4) (b) (4)	14 Sep 2020 18:35:49

**US3292103**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Kristy Trevino (b) (4) (b) (4)	14 Sep 2020 18:35:49

**US3292103**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	14 Sep 2020 18:36:19

**US3292103**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Sep 2020 18:36:19

**US3292103**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 16:36:27



**US3292103**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 16:36:27

**US3292103**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Sep 2020 16:36:27

**US3292103**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 16:36:27

**US3292103**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 16:36:32

**US3292103**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Sep 2020 16:36:32

**US3292103**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 16:04:11

**US3292103**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 16:04:11

**US3292103**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Sep 2020 16:04:11



**US3292103**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 16:04:11

**US3292103**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 16:04:15

**US3292103**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Sep 2020 16:04:15

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:55:50**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:33:45

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:55:50**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '6 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 16:33:45

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:55:50**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	06 Oct 2020 16:33:45

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:55:50**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	06 Oct 2020 16:33:45

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:50**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:35:51



**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:50**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '6 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 16:35:51

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:50**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User entered '10:27'	(b) (4), (b) (6)	06 Oct 2020 16:35:51

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:50**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '6 Oct 2020 10:27'	System	06 Oct 2020 16:35:51

US3292103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:50

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.3' C	(b) (4), (b) (6)	06 Oct 2020 16:35:51

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:50**

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	06 Oct 2020 16:35:51

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:50**

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:35:51

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '70'	(b) (4), (b) (6)	06 Oct 2020 16:35:51

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:50**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	06 Oct 2020 16:35:51



US3292103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '12'	(b) (4), (b) (6)	06 Oct 2020 16:35:51

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	06 Oct 2020 16:35:51

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:50**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '132'	(b) (4), (b) (6)	06 Oct 2020 16:35:51

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Oct 2020 16:35:51

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:50**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '77'	(b) (4), (b) (6)	06 Oct 2020 16:35:51

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Oct 2020 16:35:51

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 10:55:50**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:35:59

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 10:55:50**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:35:59



**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:55:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 21:47:17

US3292103

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '6 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 21:47:17

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:55:50**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:40'	(b) (4), (b) (6)	06 Oct 2020 21:47:17

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:55:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '6 Oct 2020 10:40'	System	06 Oct 2020 21:47:17

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:37:14

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Oct 2020 16:37:14

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered 'Day 64'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-10-08T11:48:53', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '44c540a7-7cfe-4c62-83b5-9dd079dc03b1'	System	08 Oct 2020 16:49:09
User entered 'No (N)'	System	08 Oct 2020 16:49:09



**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

Have you been exposed to someone with 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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-10-08T11:48:59', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '44c540a7-7cfe-4c62-83b5-9dd079dc03b1'	System	08 Oct 2020 16:49:09
User entered 'No (N)'	System	08 Oct 2020 16:49:09

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-10-08T11:49:07', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '44c540a7-7cfe-4c62-83b5-9dd079dc03b1' User entered '08 Oct 2020 11:49:07'	System	08 Oct 2020 16:49:09
	System	08 Oct 2020 16:49:09

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered '08 Oct 2020 00:01'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered '12 Oct 2020 23:59'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered 'Day 71'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-10-15T14:00:10', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'e541bc98-bdc7-45a7-97e7-89f9e659b405'	System	15 Oct 2020 19:00:40
User entered 'No (N)'	System	15 Oct 2020 19:00:40

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

Have you been exposed to someone with 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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-10-15T14:00:16', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'e541bc98-bdc7-45a7-97e7-89f9e659b405'	System	15 Oct 2020 19:00:40
User entered 'No (N)'	System	15 Oct 2020 19:00:40

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-10-15T14:00:21', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'e541bc98-bdc7-45a7-97e7-89f9e659b405'	System	15 Oct 2020 19:00:40
User entered '15 Oct 2020 14:00:21'	System	15 Oct 2020 19:00:40



**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered '15 Oct 2020 00:01'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered '19 Oct 2020 23:59'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered 'Day 78'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-10-22T13:36:41', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'fd5f2b16-fb73-4b3d-8a69-995dc5d21d52'	System	22 Oct 2020 18:38:02
User entered 'No (N)'	System	22 Oct 2020 18:38:02

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

Have you been exposed to someone with 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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-10-22T13:36:50', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'fd5f2b16-fb73-4b3d-8a69-995dc5d21d52'	System	22 Oct 2020 18:38:02
User entered 'No (N)'	System	22 Oct 2020 18:38:02

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-10-22T13:37:05', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'fd5f2b16-fb73-4b3d-8a69-995dc5d21d52'	System	22 Oct 2020 18:38:02
User entered '22 Oct 2020 13:37:05'	System	22 Oct 2020 18:38:02

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered '22 Oct 2020 00:01'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered '26 Oct 2020 23:59'	System	08 Aug 2020 23:39:00



**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered 'Day 92'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-11-06T12:12:19', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '34ab9771-67ed-480b-9615-a31a3ed06c9d'	System	06 Nov 2020 20:12:42
User entered 'No (N)'	System	06 Nov 2020 20:12:42

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

Have you been exposed to someone with 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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-11-06T12:12:29', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '34ab9771-67ed-480b-9615-a31a3ed06c9d'	System	06 Nov 2020 20:12:42
User entered 'No (N)'	System	06 Nov 2020 20:12:42

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-11-06T12:12:36', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '34ab9771-67ed-480b-9615-a31a3ed06c9d' User entered '06 Nov 2020 12:12:36'	System	06 Nov 2020 20:12:42

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered '05 Nov 2020 00:01'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered '09 Nov 2020 23:59'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered 'Day 99'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-11-12T17:40:40', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '0fbca193-f4d6-41a6-af77-bacf456164e2'	System	13 Nov 2020 01:40:54
User entered 'No (N)'	System	13 Nov 2020 01:40:54



**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

Have you been exposed to someone with 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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-11-12T17:40:45', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '0fbca193-f4d6-41a6-af77-bacf456164e2'	System	13 Nov 2020 01:40:54
User entered 'No (N)'	System	13 Nov 2020 01:40:54

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-11-12T17:40:52', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '0fbca193-f4d6-41a6-af77-bacf456164e2' User entered '12 Nov 2020 17:40:52'	System	13 Nov 2020 01:40:54
	System	13 Nov 2020 01:40:54

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered '12 Nov 2020 00:01'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 23:39:00
User entered '16 Nov 2020 23:59'	System	08 Aug 2020 23:39:00

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '05 Oct 2020 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '09 Oct 2020 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '12 Oct 2020 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '16 Oct 2020 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '19 Oct 2020 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '23 Oct 2020 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '26 Oct 2020 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '30 Oct 2020 23:59'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '02 Nov 2020 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '06 Nov 2020 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '09 Nov 2020 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '13 Nov 2020 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-11-19T17:35:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '999b04c3-53b7-459d-a8ff-c15ac8665d1b'	System	19 Nov 2020 23:36:35
User entered 'Yes (Y)'	System	19 Nov 2020 23:36:35



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

Have you been exposed to someone with 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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-11-19T17:36:04', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '999b04c3-53b7-459d-a8ff-c15ac8665d1b'	System	19 Nov 2020 23:36:35
User entered 'No (N)'	System	19 Nov 2020 23:36:35

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-11-19T17:36:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '999b04c3-53b7-459d-a8ff-c15ac8665d1b' User entered 'No (N)'	System	19 Nov 2020 23:36:35

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-11-19T17:35:53', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '999b04c3-53b7-459d-a8ff-c15ac8665d1b' User entered 'Yes (Y)'	System	19 Nov 2020 23:36:35
	System	19 Nov 2020 23:36:35

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Please 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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-11-19T17:36:12', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '999b04c3-53b7-459d-a8ff-c15ac8665d1b'	System	19 Nov 2020 23:36:35
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Nov 2020 23:36:35

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-11-19T17:36:24', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '999b04c3-53b7-459d-a8ff-c15ac8665d1b' User entered '19 Nov 2020 17:36:24'	System	19 Nov 2020 23:36:35
	System	19 Nov 2020 23:36:35

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '16 Nov 2020 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '20 Nov 2020 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-11-23T10:32:41', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'dba4b2dd-453d-43c8-9607-332d6653ffa0'	System	23 Nov 2020 16:32:58
User entered 'No (N)'	System	23 Nov 2020 16:32:58

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Have you been exposed to someone with 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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-11-23T10:32:47', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'dba4b2dd-453d-43c8-9607-332d6653ffa0'	System	23 Nov 2020 16:32:58
User entered 'No (N)'	System	23 Nov 2020 16:32:58

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-11-23T10:32:55', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'dba4b2dd-453d-43c8-9607-332d6653ffa0'	System	23 Nov 2020 16:32:58
User entered '23 Nov 2020 10:32:55'	System	23 Nov 2020 16:32:58

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 16:46:46



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '10 Oct 2022 00:01'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:46
Amendment Manager: User entered '14 Oct 2022 23:59'	System	19 Nov 2020 16:46:46

**US3292103**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 19:43:56

**US3292103**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 19:43:56

**US3292103**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Oct 2020 19:43:56

**US3292103**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 19:43:56

**US3292103**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 19:43:59



**US3292103**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Oct 2020 19:43:59

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 26 Nov 2020 10:55:50**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	20 Nov 2020 21:10:09

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:37:58
User entered 'USA-US072-2020-mRNA-1273-P301000013'	System	23 Nov 2020 23:37:47
User entered 'New'	(b) (4), (b) (6)	23 Nov 2020 23:37:47

US3292103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:50

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Cerebral injuries NEC, PT: Subdural haematoma, LLT: Subdural hematoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 21:52:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 21:52:05
Data point term sent to Coder	System	20 Nov 2020 21:51:20
User entered 'Subdural Hematoma'	Antonio Gutierrez (b) (4) (b) (4)	20 Nov 2020 21:51:16

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	20 Nov 2020 21:51:16

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Antonio Gutierrez (b) (4)	20 Nov 2020 21:51:16

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Antonio Gutierrez (b) (4)	20 Nov 2020 21:51:16

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '14 Nov 2020'	Antonio Gutierrez (b) (4)	20 Nov 2020 21:51:16



**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

**Start time (00:00-23:59)**

Audit	User	Time (GMT)
User entered empty.	Antonio Gutierrez (b) (4)	20 Nov 2020 21:51:16

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 21:51:16

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	20 Nov 2020 21:51:16

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Antonio Gutierrez (b) (4)	20 Nov 2020 21:51:16

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Antonio Gutierrez (b) (4)	20 Nov 2020 21:51:16

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 21:51:16

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Antonio Gutierrez (b) (4)	20 Nov 2020 21:51:16

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	20 Nov 2020 21:51:16



**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Antonio Gutierrez (b) (4)	20 Nov 2020 21:51:16

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Antonio Gutierrez (b) (4)	20 Nov 2020 21:51:16

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered 'I'	Antonio Gutierrez (b) (4)	20 Nov 2020 21:51:16

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '15 Nov 2020'	Antonio Gutierrez (b) (4)	20 Nov 2020 21:51:16

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '17 Nov 2020'	Antonio Gutierrez (b) (4)	20 Nov 2020 21:51:16

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	20 Nov 2020 21:51:16

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered '3'	Antonio Gutierrez (b) (4)	20 Nov 2020 21:51:16

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Antonio Gutierrez (b) (4)	20 Nov 2020 21:51:16



**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Antonio Gutierrez (b) (4)	20 Nov 2020 21:51:16

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Antonio Gutierrez (b) (4)	20 Nov 2020 21:51:16

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	20 Nov 2020 21:51:16

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	20 Nov 2020 21:51:16

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Antonio Gutierrez (b) (4)	20 Nov 2020 21:51:16

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[None](#)

Audit	User	Time (GMT)
User entered '0'	Antonio Gutierrez (b) (4)	20 Nov 2020 21:51:16

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Antonio Gutierrez (b) (4)	20 Nov 2020 21:51:16

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered 'I'	Antonio Gutierrez (b) (4)	20 Nov 2020 21:51:16



**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Antonio Gutierrez (b) (4)	20 Nov 2020 21:51:16

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Antonio Gutierrez (b) (4)	20 Nov 2020 21:51:16

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Patient called staff on 20NOV2020 to report that she had been hospitalized for three days due to a subdural hematoma suffered after a fall. Patient does have a medical history of rod implant due to scoliosis and a total hip replacement due to Rheumatoid arthritis, which she claims, contributed to her fall. Patient states she was tested for COVID-19 and tests came back negative. Intake and discharge CT scans completed and Keppra was prescribed while inpatient to prevent seizures. Medical records will be requested asap.'	Antonio Gutierrez (b) (4)	20 Nov 2020 21:51:16

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Nov 2020 21:51:16

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Nov 2020 21:51:16

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Nov 2020 21:51:16

US3292103

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 26 Nov 2020 10:55:50**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:09:16

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 16:55:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 16:55:39
Data point term sent to Coder Coding entries removed.	System Victoria Hernandez (b) (4) (b) (4)	17 Sep 2020 16:55:05 17 Sep 2020 16:54:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:12:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:12:21
Data point term sent to Coder User entered 'Tylenol'	System (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 16:10:48 11 Aug 2020 16:10:08



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:10:08

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:50

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the location of JOINT PAIN (e.g. Generalized or Localized- specify part or area). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:50:19
Query 'Per DM CLR: Please update the indication to reflect the location of JOINT PAIN (e.g. Generalized or Localized- specify part or area). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	17 Sep 2020 16:54:26
User entered 'GENERALIZED JOINT PAIN' reason for change: Data Entry Error	(b) (4)	17 Sep 2020 16:54:10
User opened query 'Per DM CLR: Please update the indication to reflect the location of JOINT PAIN (e.g. Generalized or Localized- specify part or area). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 11:51:39
User entered 'joint pain'	(b) (4), (b) (6)	11 Aug 2020 16:10:08

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '325'	(b) (4), (b) (6)	11 Aug 2020 16:10:08

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:50

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Aug 2020 16:10:08

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:10:08

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	11 Aug 2020 16:10:08

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:10:08

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 16:10:08



US3292103

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:10:08

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:50

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)	12 Aug 2020 16:10:13
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	11 Aug 2020 16:10:14
answered with 'Medication is ongoing, correct as entered' (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	11 Aug 2020 16:10:08
User entered 'un UNK 2000'	(b) (4), (b) (6)	11 Aug 2020 16:10:08

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:10:08

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:10:08

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:50**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:10:08

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:10:08

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 16:10:08

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 16:10:08



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 16:10:08

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM CITRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 06:52:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 06:52:18
Data point term sent to Coder	System	11 Aug 2020 16:11:50
User entered 'Magnesium citrate'	(b) (4), (b) (6)  (b) (4)	11 Aug 2020 16:11:05

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:11:05

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:55:50**

[Indication](#)

Audit	User	Time (GMT)
User entered 'General health'	(b) (4), (b) (6)	11 Aug 2020 16:11:05

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:50

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:52:10
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'UPDATED PER SUBJECT' (Site from DM).	Victoria Hernandez (b) (4)	17 Sep 2020 16:58:27
User entered '250' reason for change: New Information	(b) (4)	17 Sep 2020 16:57:50
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 11:51:17
User entered 'I'	(b) (4), (b) (6)	11 Aug 2020 16:11:05

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:50

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)' reason for change: New Information	Victoria Hernandez (b) (4)	17 Sep 2020 16:57:50
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	11 Aug 2020 16:11:05

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:11:05

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:55:50**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Aug 2020 16:11:05



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:11:05

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:50

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 16:11:05

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:55:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:11:05

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:50

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)	12 Aug 2020 16:10:22
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	11 Aug 2020 16:11:08
answered with 'Medication is ongoing, correct as entered' (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	11 Aug 2020 16:11:05
User entered 'un UNK 2014'	(b) (4), (b) (6)	11 Aug 2020 16:11:05

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:50

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:11:05

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:55:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:11:05

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:55:50**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:11:05

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:11:05



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:55:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 16:11:05

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 16:11:05

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 16:11:05

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 19:04:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 19:04:07
Data point term sent to Coder	System	26 Oct 2020 17:57:34
Coding entries removed.	Victoria Hernandez (b) (4) (b) (4)	26 Oct 2020 17:57:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:13:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:13:20
Data point term sent to Coder	System	11 Aug 2020 16:11:52
User entered 'allegra'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 16:11:38

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:11:38

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:50

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	(b) (4) 26 Oct 2020 17:57:47
User entered 'SEASONAL ALLERGIES' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	(b) (4) 26 Oct 2020 17:57:31
User opened query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 02:39:03
User entered 'allergies'	(b) (4), (b) (6)	11 Aug 2020 16:11:38

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:50

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:53:15
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'UPDATED PER SUBJECT' (Site from DM).	Victoria Hernandez (b) (4) (b) (4)	17 Sep 2020 17:02:36
User entered '180' reason for change: New Information	Victoria Hernandez (b) (4) (b) (4)	17 Sep 2020 17:00:13
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 10:37:13
User entered '20'	(b) (4), (b) (6)	11 Aug 2020 16:11:38

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:50

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Aug 2020 16:11:38



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:11:38

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:55:50**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	11 Aug 2020 16:11:38

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:11:38

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:50

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 16:11:38

US3292103

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:55:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:11:38

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:50

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)	12 Aug 2020 16:10:29
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	11 Aug 2020 16:12:18
answered with 'Medication is ongoing, correct as entered' (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	11 Aug 2020 16:11:38
User entered 'un UNK 2019'	(b) (4), (b) (6)	11 Aug 2020 16:11:38

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:11:38

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:55:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:11:38



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:11:38

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:11:38

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:55:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 16:11:38

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 16:11:38

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 16:11:38

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:14:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:14:16
Data point term sent to Coder	System	11 Aug 2020 16:12:57
User entered 'fish oil'	(b) (4), (b) (6)  (b) (4)	11 Aug 2020 16:12:11

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:12:11

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:50**

[Indication](#)

Audit	User	Time (GMT)
User entered 'general health'	(b) (4), (b) (6)	11 Aug 2020 16:12:11



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:50

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:54:12
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'UPDATED PER SUBJECT' (Site from DM).	Victoria Hernandez (b) (4)	17 Sep 2020 17:04:29
User entered '1000' reason for change: New Information	(b) (4)	17 Sep 2020 17:04:07
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 11:50:56
User entered 'I'	(b) (4), (b) (6)	11 Aug 2020 16:12:11

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:50

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)' reason for change: New Information	Victoria Hernandez (b) (4)	17 Sep 2020 17:04:07
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	11 Aug 2020 16:12:11

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:12:11

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:50**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Aug 2020 16:12:11

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:12:11

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:50

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 16:12:11

US3292103

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:12:11

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:50

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)	12 Aug 2020 16:10:39
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 16:12:13
answered with 'Medication is ongoing, correct as entered' (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	11 Aug 2020 16:12:11
User entered 'un UNK 2015'	(b) (4), (b) (6)	11 Aug 2020 16:12:11



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:12:11

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:12:11

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:12:11

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:12:11

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 16:12:11

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 16:12:11

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 16:12:11

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:00:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:00:01



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:50

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, COMBINATIONS, ATC: MULTIVITAMINS WITH MINERALS, PRODUCT: ASCORBIC ACID;BIOTIN;CALCIUM;CALCIUM PHOSPHATE DIBASIC;CHROMIC CHLORIDE;CUPRIC OXIDE;CYANOCOBALAMIN;FERROUS FUMARATE;FOLIC ACID;MAGNESIUM OXIDE;MANGANESE SULFATE;NICKEL SULFATE;NICOTINAMIDE;PANTOTHENIC ACID;PHYTOMENADIONE;POTASSIUM CHLORIDE;POTASSIUM IODIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SODIUM METASILICATE;SODIUM MOLYBDATE;SODIUM SELENATE;THIAMINE MONONITRATE;TOCOPHERYL ACETATE;VITAMIN D NOS;ZINC OXIDE, PRODUCTSYNONYM: CENTRUM SILVER [ASCORBIC ACID;BIOTIN;CALCIUM;CALCIUM PHOSPHATE DIBASIC;CHROMIC CHLORIDE;CUPRIC OXIDE;CYANOCOBALAMIN;FERROUS FUMARATE;FOLIC ACID;MAGNESIUM OXIDE;MANGANESE SULFATE;NICKEL SULFATE;NICOTINAMIDE;PANTOTHENIC ACID;PHYTOMENADIONE;POTASSIUM CHLORIDE;POTASSIUM IODIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SODIUM METASILICATE;SODIUM MOLYBDATE;SODIUM SELENATE;THIAMINE MONONITRATE;TOCOPHERYL ACETATE;VITAMIN D NOS;ZINC OXIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 17:31:53
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 17:31:53

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:15:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:15:22
Data point term sent to Coder	System	11 Aug 2020 16:14:01
User entered 'centrum silver'	(b) (4), (b) (6)  (b) (4)	11 Aug 2020 16:13:18

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:13:18

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:50**

[Indication](#)

Audit	User	Time (GMT)
User entered 'general health'	(b) (4), (b) (6)	11 Aug 2020 16:13:18

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:50**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	11 Aug 2020 16:13:18

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:50**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	11 Aug 2020 16:13:18

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:13:18

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:50

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Aug 2020 16:13:18



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:13:18

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:50**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 16:13:18

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:13:18

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:50

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)	12 Aug 2020 16:10:45
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 16:13:21
answered with 'Medication is ongoing, correct as entered' (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	11 Aug 2020 16:13:18
User entered 'un UNK 2015'	(b) (4), (b) (6)	11 Aug 2020 16:13:18

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:13:18

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:13:18

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:50**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:13:18

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:13:18



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 16:13:18

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 16:13:18

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 16:13:18

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIHEMORRHAGICS, ATC: VITAMIN K AND OTHER HEMOSTATICS, ATC: VITAMIN K, PRODUCT: VITAMIN K NOS, PRODUCTSYNONYM: VITAMIN K [VITAMIN K NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:15:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:15:21
Data point term sent to Coder	System	11 Aug 2020 16:14:02
User entered 'Vitamin K'	(b) (4), (b) (6)  (b) (4)	11 Aug 2020 16:14:01

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:14:01

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:50**

[Indication](#)

Audit	User	Time (GMT)
User entered 'General health'	(b) (4), (b) (6)	11 Aug 2020 16:14:01

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:50

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:55:08
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'UPDATED PERSUBJECT' (Site from DM).	Victoria Hernandez (b) (4)	17 Sep 2020 17:13:37
User entered '100' reason for change: New Information	(b) (4)	17 Sep 2020 17:13:13
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 11:52:40
User entered 'I'	(b) (4), (b) (6)	11 Aug 2020 16:14:01

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:50

[Dose unit](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	26 Oct 2020 18:01:08
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 18:00:58
User opened query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 05:59:07
User entered 'Other (OTHER)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	17 Sep 2020 17:13:13
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	11 Aug 2020 16:14:01



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty; reason for change New Information	Victoria Hernandez (b) (4)	(b) (4) 26 Oct 2020 18:00:58
User entered 'mcg' reason for change: New Information	Victoria Hernandez (b) (4)	(b) (4) 17 Sep 2020 17:13:13
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:14:01

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:50

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Aug 2020 16:14:01

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:14:01

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:50**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 16:14:01

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:14:01

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:50

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)	12 Aug 2020 16:10:51
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 16:14:04
answered with 'Medication is ongoing, correct as entered' (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	11 Aug 2020 16:14:01
User entered 'un UNK 2015'	(b) (4), (b) (6)	11 Aug 2020 16:14:01

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:14:01

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:14:01



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:14:01

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:14:01

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 16:14:01

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 16:14:01

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 16:14:01

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:16:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:16:12
Data point term sent to Coder	System	11 Aug 2020 16:15:04
User entered 'vitamin D3'	(b) (4), (b) (6) (b) (4) (b) (4)	11 Aug 2020 16:14:41

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:14:41

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:50**

[Indication](#)

Audit	User	Time (GMT)
User entered 'GENERAL HEALTH'	(b) (4), (b) (6)	11 Aug 2020 16:14:41



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:50

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:55:43
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'UPDATED PER SUBJECT' (Site from DM).	Victoria Hernandez (b) (4)	17 Sep 2020 17:16:52
User entered '1000' reason for change: New Information	(b) (4)	17 Sep 2020 17:16:11
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 11:52:19
User entered 'I'	(b) (4), (b) (6)	11 Aug 2020 16:14:41

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:50**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'TU (IU)' reason for change: New Information	Victoria Hernandez (b) (4)	17 Sep 2020 17:16:11
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	11 Aug 2020 16:14:41

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:14:41

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:50

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Aug 2020 16:14:41

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:14:41

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:50**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 16:14:41

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:14:41

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:50

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)	12 Aug 2020 16:10:57
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 16:14:44
answered with 'Medication is ongoing, correct as entered' (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	11 Aug 2020 16:14:41
User entered 'UN UNK 2015'	(b) (4), (b) (6)	11 Aug 2020 16:14:41



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:14:41

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:14:41

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:14:41

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:14:41

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 16:14:41

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 16:14:41

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 16:14:41

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:17:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:17:09
Data point term sent to Coder	System	11 Aug 2020 16:16:05
User entered 'CALCIUM'	(b) (4), (b) (6)  (b) (4)	11 Aug 2020 16:15:08



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:15:08

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:55:50**

[Indication](#)

Audit	User	Time (GMT)
User entered 'GENERAL HEALTH'	(b) (4), (b) (6)	11 Aug 2020 16:15:08

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:50

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:55:50
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'UPDATED PER SUBJECT' (Site from DM).	Victoria Hernandez (b) (4)	17 Sep 2020 17:23:10
User entered '600' reason for change: New Information	(b) (4)	17 Sep 2020 17:22:55
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 11:50:37
User entered 'I'	(b) (4), (b) (6)	11 Aug 2020 16:15:08

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:50

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)' reason for change: New Information	Victoria Hernandez (b) (4)	17 Sep 2020 17:22:55
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	11 Aug 2020 16:15:08

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:15:08

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:50

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Aug 2020 16:15:08

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:15:08

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:50

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 16:15:08



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:15:08

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:50

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)	12 Aug 2020 16:11:38
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 16:15:11
answered with 'Medication is ongoing, correct as entered' (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	11 Aug 2020 16:15:08
User entered 'UN UNK 2015'	(b) (4), (b) (6)	11 Aug 2020 16:15:08

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:15:08

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:55:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:15:08

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:15:08

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:55:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:15:08

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:55:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 16:15:08

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 16:15:08



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 16:15:08

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:50

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 13:28:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 13:28:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: VITAMIN B - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:17:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:17:09
Data point term sent to Coder	System	11 Aug 2020 16:16:05
User entered 'Vitamin b'	(b) (4), (b) (6)  	11 Aug 2020 16:15:44

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:15:44

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:55:50**

[Indication](#)

Audit	User	Time (GMT)
User entered 'General health'	(b) (4), (b) (6)	11 Aug 2020 16:15:44

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:50

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:56:40
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'UPDATED PER SUBJECT' (Site from DM).	Victoria Hernandez (b) (4)	17 Sep 2020 17:24:37
User entered '1000' reason for change: New Information	(b) (4)	17 Sep 2020 17:24:21
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 11:52:02
User entered 'I'	(b) (4), (b) (6)	11 Aug 2020 16:15:44

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:50

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)' reason for change: New Information	Victoria Hernandez (b) (4)	17 Sep 2020 17:24:21
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	11 Aug 2020 16:15:44

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:15:44

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:50

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Aug 2020 16:15:44



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:15:44

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:50

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 16:15:44

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:15:44

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:50

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)	12 Aug 2020 16:11:44
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 16:15:49
answered with 'Medication is ongoing, correct as entered' (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	11 Aug 2020 16:15:44
User entered 'un UNK 2015'	(b) (4), (b) (6)	11 Aug 2020 16:15:44

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:15:44

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:55:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:15:44

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:15:44

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:15:44



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:55:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 16:15:44

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 16:15:44

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 16:15:44

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:18:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:18:13
Data point term sent to Coder	System	11 Aug 2020 16:17:11
User entered 'Metoprolol'	(b) (4), (b) (6) (b) (4) (b) (4)	11 Aug 2020 16:16:34

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:16:34

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:50

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypertension'	(b) (4), (b) (6)	11 Aug 2020 16:16:34

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:50

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '25'	(b) (4), (b) (6)	11 Aug 2020 16:16:34

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:50

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Aug 2020 16:16:34



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:16:34

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:50**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Aug 2020 16:16:34

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:16:34

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:50**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 16:16:34

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:16:34

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:50

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)	12 Aug 2020 16:11:50
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 16:16:41
answered with 'Medication is ongoing, correct as entered' (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	11 Aug 2020 16:16:34
User entered 'un UNK 2005'	(b) (4), (b) (6)	11 Aug 2020 16:16:34

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:16:34

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:16:34



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:50**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:16:34

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:16:34

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 16:16:34

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 16:16:34

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 16:16:34

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:19:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:19:09
Data point term sent to Coder	System	11 Aug 2020 16:18:12
User entered 'amlodipine'	(b) (4), (b) (6)	11 Aug 2020 16:17:17

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:17:17

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:50

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypertension'	(b) (4), (b) (6)	11 Aug 2020 16:17:17



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:50**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	(b) (4), (b) (6)	11 Aug 2020 16:17:17

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:50

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Aug 2020 16:17:17

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:17:17

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:50**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Aug 2020 16:17:17

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:17:17

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:50

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 16:17:17

US3292103

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:17:17

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:50

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)	12 Aug 2020 16:11:56
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 16:17:22
answered with 'Medication is ongoing, correct as entered' (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	11 Aug 2020 16:17:17
User entered 'un UNK 2005'	(b) (4), (b) (6)	11 Aug 2020 16:17:17



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:17:17

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:17:17

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:50**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:17:17

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:17:17

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 16:17:17

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 16:17:17

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 16:17:17

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:50

[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)	11 Aug 2020 16:19:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:19:10
Data point term sent to Coder	System	11 Aug 2020 16:18:13
User entered 'atorvastatin'	(b) (4), (b) (6) (b) (4) (b) (4)	11 Aug 2020 16:18:00



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:18:00

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:55:50**

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypercholesterolemia'	(b) (4), (b) (6)	11 Aug 2020 16:18:00

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:50

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	(b) (4), (b) (6)	11 Aug 2020 16:18:00

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:50

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Aug 2020 16:18:00

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:18:00

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:55:50**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Aug 2020 16:18:00

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:18:00

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:55:50**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 16:18:00



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:18:00

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 13:10:31
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	11 Aug 2020 16:18:00
User entered 'un UNK 2015'	(b) (4), (b) (6)	11 Aug 2020 16:18:00

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:18:00

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:55:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:18:00

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:18:00

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:18:00

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:55:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 16:18:00

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 16:18:00



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 16:18:00

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:50

[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)	17 Aug 2020 08:37:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 08:37:20
Data point term sent to Coder	System	11 Aug 2020 16:19:14
User entered 'lostartan'	(b) (4), (b) (6) (b) (4) (b) (4)	11 Aug 2020 16:18:35

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:55:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:18:35

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:55:50**

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypertension'	(b) (4), (b) (6)	11 Aug 2020 16:18:35

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:50

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	(b) (4), (b) (6)	11 Aug 2020 16:18:35

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:50

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Aug 2020 16:18:35

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:18:35

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:55:50**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Aug 2020 16:18:35



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:18:35

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:55:50**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 16:18:35

US3292103

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:55:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:18:35

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:50

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)	12 Aug 2020 16:12:10
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 16:18:38
answered with 'Medication is ongoing, correct as entered' (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	11 Aug 2020 16:18:35
User entered 'un UNK 2005'	(b) (4), (b) (6)	11 Aug 2020 16:18:35

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:18:35

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:55:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:18:35

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:18:35

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:18:35



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:55:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 16:18:35

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 16:18:35

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 16:18:35

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: THYROID, PRODUCTSYNONYM: ARMOUR THYROID - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:06:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:06:12
Data point term sent to Coder	System	11 Aug 2020 16:20:15
User entered 'armour thyroid'	(b) (4), (b) (6) (b) (4) (b) (4)	11 Aug 2020 16:19:39

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:55:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:19:39

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:55:50**

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypothyroid'	(b) (4), (b) (6)	11 Aug 2020 16:19:39

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:50

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '60'	(b) (4), (b) (6)	11 Aug 2020 16:19:39

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:50

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'ug (ug)'	(b) (4), (b) (6)	11 Aug 2020 16:19:39



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:19:39

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:55:50**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Aug 2020 16:19:39

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:19:39

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:55:50**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 16:19:39

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:19:39

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:50

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)	12 Aug 2020 16:12:16
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	11 Aug 2020 16:19:41
answered with 'Medication is ongoing, correct as entered' (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	11 Aug 2020 16:19:39
User entered 'un UNK 2015'	(b) (4), (b) (6)	11 Aug 2020 16:19:39

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:19:39

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:55:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:19:39



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:19:39

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:19:39

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:55:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 16:19:39

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 16:19:39

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 16:19:39

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:55:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: PROGESTOGENS, ATC: PREGNEN (4) DERIVATIVES, PRODUCT: PROGESTERONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:11:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:11:16
Data point term sent to Coder	System	11 Aug 2020 16:20:15
User entered 'progesterone'	(b) (4), (b) (6) (b) (4) (b) (4)	11 Aug 2020 16:20:14

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:20:14

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:50**

[Indication](#)

Audit	User	Time (GMT)
User entered 'low progesterone'	(b) (4), (b) (6)	11 Aug 2020 16:20:14



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:50**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '200'	(b) (4), (b) (6)	11 Aug 2020 16:20:14

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:55:50

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Aug 2020 16:20:14

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:55:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:20:14

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:50**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Aug 2020 16:20:14

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:55:50

If frequency is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:20:14

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:55:50

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 16:20:14

US3292103

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:20:14

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:55:50

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)	12 Aug 2020 16:12:28
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 16:20:17
answered with 'Medication is ongoing, correct as entered' (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	11 Aug 2020 16:20:14
User entered 'un UNK 2015'	(b) (4), (b) (6)	11 Aug 2020 16:20:14



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:20:14

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:20:14

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:55:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:20:14

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:55:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:20:14

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 16:20:14

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 16:20:14

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 16:20:14

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:50

[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: ESOMEPRAZOLE MAGNESIUM, PRODUCTSYNONYM: NEXIUM [ESOMEPRAZOLE MAGNESIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 19:15:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 19:15:55
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: ESOMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 12:50:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 12:50:23
Data point term sent to Coder	System	11 Aug 2020 16:21:16
User entered 'Nexium'	(b) (4), (b) (6) (b) (4) (b) (4)	11 Aug 2020 16:20:47



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:20:47

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:55:50**

[Indication](#)

Audit	User	Time (GMT)
User entered 'GERD'	(b) (4), (b) (6)	11 Aug 2020 16:20:47

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:50

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	(b) (4), (b) (6)	11 Aug 2020 16:20:47

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:50

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Aug 2020 16:20:47

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:20:47

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:55:50**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Aug 2020 16:20:47

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:55:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:20:47

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:55:50**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Aug 2020 16:20:47



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:20:47

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:50

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)	12 Aug 2020 16:12:34
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 16:20:49
answered with 'Medication is ongoing, correct as entered' (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	11 Aug 2020 16:20:47
User entered 'un UNK 2000'	(b) (4), (b) (6)	11 Aug 2020 16:20:47

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:50

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:20:47

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:55:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:20:47

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:20:47

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 16:20:47

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:55:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 16:20:47

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 16:20:47



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 16:20:47

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:55:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: LEVETIRACETAM, PRODUCTSYNONYM: KEPPRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 22:18:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 22:18:04
Data point term sent to Coder	System	20 Nov 2020 22:16:47
User entered 'Keppra'	Antonio Gutierrez (b) (4)	20 Nov 2020 22:16:43

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:55:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	20 Nov 2020 22:16:43

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:55:50**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Seizure prevention following subdural hematoma'	Antonio Gutierrez (b) (4)	20 Nov 2020 22:16:43

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:55:50

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '750'	Antonio Gutierrez (b) (4)	20 Nov 2020 22:16:43

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:55:50

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Antonio Gutierrez (b) (4)	20 Nov 2020 22:16:43

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:55:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Antonio Gutierrez (b) (4)	20 Nov 2020 22:16:43

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:55:50

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Antonio Gutierrez (b) (4)	20 Nov 2020 22:16:43



US3292103

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:55:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Antonio Gutierrez (b) (4)	20 Nov 2020 22:16:43

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:55:50

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Antonio Gutierrez (b) (4)	20 Nov 2020 22:16:43

US3292103

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:55:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Antonio Gutierrez (b) (4)	20 Nov 2020 22:16:43

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:55:50

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Nov 2020'	Antonio Gutierrez (b) (4)	20 Nov 2020 22:16:43

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:55:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Antonio Gutierrez (b) (4)	20 Nov 2020 22:16:43

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:55:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	20 Nov 2020 22:16:43

US3292103

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:55:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Antonio Gutierrez (b) (4)	20 Nov 2020 22:16:43

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:55:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Antonio Gutierrez (b) (4)	20 Nov 2020 22:16:43



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:55:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Nov 2020 22:16:43

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 22:16:43

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:55:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Nov 2020 22:16:43

US3292103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:55:50

Were any concomitant procedures performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	20 Nov 2020 22:14:09

US3292103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:55:50

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Nov 2020'	Antonio Gutierrez (b) (4)	20 Nov 2020 22:14:29

US3292103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:55:50

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'Head CT'	Antonio Gutierrez (b) (4)	20 Nov 2020 22:14:29

**US3292103**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Antonio Gutierrez (b) (4)	20 Nov 2020 22:14:29

US3292103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:55:50

If indication is Other, specify

Audit	User	Time (GMT)
User entered empty.	Antonio Gutierrez (b) (4)	20 Nov 2020 22:14:29



**US3292103**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 26 Nov 2020 10:55:50**

**Procedure/Surgery date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered '17 Nov 2020'	Antonio Gutierrez (b) (4)	20 Nov 2020 22:14:49

**US3292103**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 26 Nov 2020 10:55:50**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'Head CT'	Antonio Gutierrez (b) (4)	20 Nov 2020 22:14:49

**US3292103**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 26 Nov 2020 10:55:50**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Antonio Gutierrez (b) (4)	20 Nov 2020 22:14:49

**US3292103**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 26 Nov 2020 10:55:50**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Antonio Gutierrez (b) (4)	20 Nov 2020 22:14:49

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:50**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:38:40
User entered 'USA-US072-2020-MRNA-1273-P301000013'	System	23 Nov 2020 23:37:47

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:50**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:38:40
User entered 'Yes (Y)'	System	23 Nov 2020 23:37:47

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:50**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:38:40
User entered 'No (N)'	System	23 Nov 2020 23:37:47

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:50**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:38:40
User entered 'No (N)'	System	23 Nov 2020 23:37:47



**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:38:40
User entered 'Yes (Y)'	System	23 Nov 2020 23:37:47

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:50**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:38:40
User entered 'No (N)'	System	23 Nov 2020 23:37:47

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:50**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:38:40
User entered 'No (N)'	System	23 Nov 2020 23:37:47

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:50**

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:38:40
User entered 'No (N)'	System	23 Nov 2020 23:37:47

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:50**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:38:40
User entered 'Douglas'	System	23 Nov 2020 23:37:47

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:50**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:38:40
User entered 'Denham'	System	23 Nov 2020 23:37:47

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:50**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:38:40
User entered '7940 Floyd Curl Drive'	System	23 Nov 2020 23:37:47

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:50**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:38:40
User entered 'San Antonio'	System	23 Nov 2020 23:37:47



**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:50**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:38:40
User entered '78229'	System	23 Nov 2020 23:37:47

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:50**

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	23 Nov 2020 23:38:47

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:50**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Nov 2020 23:38:47

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:50**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:38:40
User entered 'USA-US072-2020-MRNA-1273-P301000013'	System	23 Nov 2020 23:37:47

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:50**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:38:40
User entered 'Yes (Y)'	System	23 Nov 2020 23:37:47

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:50**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:38:40
User entered 'No (N)'	System	23 Nov 2020 23:37:47

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:50**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:38:40
User entered 'No (N)'	System	23 Nov 2020 23:37:47

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:38:40
User entered 'Yes (Y)'	System	23 Nov 2020 23:37:47



**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:50**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:38:40
User entered 'No (N)'	System	23 Nov 2020 23:37:47

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:50**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:38:40
User entered 'No (N)'	System	23 Nov 2020 23:37:47

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:50**

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:38:40
User entered 'No (N)'	System	23 Nov 2020 23:37:47

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:50**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:38:40
User entered 'Douglas'	System	23 Nov 2020 23:37:47

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:50**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:38:40
User entered 'Denham'	System	23 Nov 2020 23:37:47

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:50**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:38:40
User entered '7940 Floyd Curl Drive'	System	23 Nov 2020 23:37:47

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:50**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:38:40
User entered 'San Antonio'	System	23 Nov 2020 23:37:47

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:50**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:38:40
User entered '78229'	System	23 Nov 2020 23:37:47



**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:50**

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	23 Nov 2020 23:38:47

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:50**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Nov 2020 23:38:47

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form (1)**

**Generated On: 26 Nov 2020 10:55:50**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '23/Nov/2020 18:38'	System	23 Nov 2020 23:38:47

US3292103

Folder: SAE USA-US072-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:55:50

**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.**

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	23 Nov 2020 23:38:47