

US3292023 (Prod: Clinical Trials of Texas, Inc)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:55:08

All time stamps listed in this document are displayed in GMT

**US3292023**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 10:55:08**

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[Participant ID](#)

US3292023

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

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US3292023

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:55:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 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

US3292023

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:08

Date of Birth (MMM yyyy)	(b) (6) 1940
Age	80
Age Units	YEARS
Age (Derived)	80
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3292023

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:08

Date of Informed Consent ( <i>dd MMM yyyy</i> )	04 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

US3292023

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:55:08

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3292023

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:55:08

Were any significant conditions reported?

Yes ☒

No ☐

US3292023

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:08

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



US3292023

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:08

Condition	SEASONAL ALLERGY: MOUNTAIN CEDAR
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)	

US3292023

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:55:08

Condition	SEASONAL ALLERGY: MOLD
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)	

US3292023

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:08

Condition	APPENDECTOMY
Start date (dd MMM yyyy)	UN UNK 1958
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 1958
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1958
Start Year (derived)	1958
Stop Month and Year (derived)	JAN 1958
Stop Year (derived)	1958

US3292023

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:08

Condition	APPENDICITIS
Start date (dd MMM yyyy)	UN UNK 1958
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 1958
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1958
Start Year (derived)	1958
Stop Month and Year (derived)	JAN 1958
Stop Year (derived)	1958

US3292023

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:08

Condition	TONSILITIS
Start date (dd MMM yyyy)	UN UNK 1946
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 1946
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1946
Start Year (derived)	1946
Stop Month and Year (derived)	JAN 1946
Stop Year (derived)	1946

US3292023

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:08

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1946
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 1946
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1946
Start Year (derived)	1946
Stop Month and Year (derived)	JAN 1946
Stop Year (derived)	1946

US3292023

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:55:08

Condition	KNEE REPLACEMENT - LEFT KNEE
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

US3292023

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:08

Condition	KNEE SURGERY - LEFT KNEE
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007



US3292023

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:08

Condition	BACK SURGERY
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JAN 1990
Stop Year (derived)	1990

US3292023

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:08

Condition	SURGERY TO PENIS
Start date (dd MMM yyyy)	UN UNK 1988
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 1988
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1988
Start Year (derived)	1988
Stop Month and Year (derived)	JAN 1988
Stop Year (derived)	1988

US3292023

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:55:08

Condition	KIDNEY SURGERY - REMOVE BENIGN SPOT ON KIDNEY
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	JAN 2006
Stop Year (derived)	2006

US3292023

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:55:08

Condition	STENT PLACEMENT
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

US3292023

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:55:08

Condition	PEYRONIES PLAQUE SURGERY
Start date (dd MMM yyyy)	UN UNK 1982
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 1982
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1982
Start Year (derived)	1982
Stop Month and Year (derived)	JAN 1982
Stop Year (derived)	1982

US3292023

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:55:08

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

US3292023

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:55:08

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

US3292023

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:55:08

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



US3292023

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 10:55:08

Condition	ATOPIC DERMITIS ON FACE
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

US3292023

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:55:08

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

US3292023

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 10:55:08

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

US3292023

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 10:55:08

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

US3292023

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 10:55:08

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

US3292023

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 10:55:08

Condition	BILATERAL CARTILAGE BUILDUP IN KNEES
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="checkbox"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

US3292023

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 10:55:08

Condition	FRACTURED BACK
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JAN 1990
Stop Year (derived)	1990

US3292023

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 10:55:08

Condition	PEYRONIE'S PLAQUE
Start date (dd MMM yyyy)	UN UNK 1982
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 1988
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1982
Start Year (derived)	1982
Stop Month and Year (derived)	JAN 1988
Stop Year (derived)	1988



US3292023

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 10:55:08

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:08

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	04 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	14:37 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 14:37
Height ( <i>xxx.x</i> )	182.1 cm
Weight ( <i>xxx.x</i> )	70.5 kg
BMI ( <i>xxx.x</i> )	21.26029 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)	

US3292023

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:08

**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

**Specify**

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

**No Risk Identified** False

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

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

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:08

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

US3292023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:55:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 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

US3292023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:08

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

What was the participant's randomization number? 184711

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 ☒

**US3292023**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 26 Nov 2020 10:55:08**

Height	ND - Not Done
Weight	ND - Not Done



US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:08

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)	04 AUG 2020
Time of assessment (00:00-23:59)	14:37 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 14:37
Temperature (xxx.x)	35.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:08

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)	04 AUG 2020
Time of assessment (00:00-23:59)	16:33 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 16:33
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3292023

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:08

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.*

US3292023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:08

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	04 AUG 2020
What was the treatment time? (00:00-23:59)	16:00 (24 HR)
Treatment Date and Time (derived)	04 AUG 2020 16:00
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

US3292023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	04 AUG 2020
Collection time ( <i>00:00-23:59</i> )	15:00 (24 HR)
Collection date and time (derived)	04 AUG 2020 15:00

US3292023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:55:08

Collection date ( <i>dd MMM yyyy</i> )			04 AUG 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:25	04 AUG 2020 15:25
Nasopharyngeal Swab 2	No		

US3292023

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:55:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:55:08

**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

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):

PC Time Stamp

04 AUG 2020 16:39

PC Open Date & Time

04 AUG 2020 16:20

PC Close Date & Time

04 AUG 2020 18:50



US3292023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:55:08

**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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

04 AUG 2020 19:45

PC Close Date & Time

05 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:55:08

**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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 05 AUG 2020 12:00

PC Close Date & Time 06 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:55:08

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 09:02

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:55:08

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 22:20

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:55:08

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 21:43

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:55:08

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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.

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

96.8 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

09 AUG 2020 20:45

---

PC Open Date & Time

09 AUG 2020 12:00

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PC Close Date & Time

10 AUG 2020 11:59

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US3292023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:55:08

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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.

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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

97.0 °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 AUG 2020 22:41

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 16:41

PC Open Date & Time

04 AUG 2020 16:20

PC Close Date & Time

04 AUG 2020 18:50



US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:55:08

**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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the  
ruler provided.

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE  
(in mm)**

Measure the largest size across any injection site swelling/hardness  
with the ruler provided.

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

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

PC Open Date & Time

04 AUG 2020 19:45

PC Close Date & Time

05 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:55:08

**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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the  
ruler provided.

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE  
(in mm)**

Measure the largest size across any injection site swelling/hardness  
with the ruler provided.

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:55:08

**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 AUG 2020 09:05

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:55:08

**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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the  
ruler provided.

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE  
(in mm)**

Measure the largest size across any injection site swelling/hardness  
with the ruler provided.

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:55:08

**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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the  
ruler provided.

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE  
(in mm)**

Measure the largest size across any injection site swelling/hardness  
with the ruler provided.

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:55:08

**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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the  
ruler provided.

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE  
(in mm)**

Measure the largest size across any injection site swelling/hardness  
with the ruler provided.

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 22:43

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:55:08

**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 ☐



US3292023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:55:08

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 16:43
PC Open Date & Time	04 AUG 2020 16:20
PC Close Date & Time	04 AUG 2020 18:50

US3292023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:55:08

**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 ☐

US3292023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:55:08

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

04 AUG 2020 19:45

PC Close Date & Time

05 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:55:08

**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 ☐

US3292023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:55:08

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

US3292023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:55:08

**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 ☒

US3292023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:55:08

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 09:06
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:55:08

**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 ☒



US3292023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:55:08

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 22:22
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:55:08

**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 ☒

US3292023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:55:08

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 21:45
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:55:08

**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 ☒

US3292023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:55:08

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 20:48
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3292023

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:55:08

**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 ☐

US3292023

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:55:08

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

US3292023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:08

Was Contact Attempted?

Yes ☒

No ☐

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

11 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3292023

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:08

Was Contact Attempted?

Yes ☒

No ☐

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

18 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292023

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:08

Was Contact Attempted?

Yes ☒

No ☐

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

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292023

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 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

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:08

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 SEP 2020
Time of assessment (00:00-23:59)	11:55 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 11:55
Temperature (xxx.x)	36.2 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:08

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 SEP 2020
Time of assessment (00:00-23:59)	13:26 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 13:26
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG



US3292023

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 SEP 2020

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

US3292023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:08

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)	1 SEP 2020
What was the treatment time? (00:00-23:59)	12:47 (24 HR)
Treatment Date and Time (derived)	1 SEP 2020 12:47
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

US3292023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	1 SEP 2020
Collection time ( <i>00:00-23:59</i> )	12:17 (24 HR)
Collection date and time (derived)	1 SEP 2020 12:17

US3292023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:55:08

Collection date ( <i>dd MMM yyyy</i> )			01 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	12:25	01 SEP 2020 12:25
Nasopharyngeal Swab 2	No		

US3292023

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:55:08

**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

98.3 °F

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

Yes ☐  
No ☒

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

PC Time Stamp 01 SEP 2020 13:30

PC Open Date & Time 01 SEP 2020 13:07

PC Close Date & Time 01 SEP 2020 15:37

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

PC Time Stamp	01 SEP 2020 22:00
PC Open Date & Time	01 SEP 2020 16:32
PC Close Date & Time	02 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:55:08

---

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

99.3 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

02 SEP 2020 23:00

---

PC Open Date & Time

02 SEP 2020 12:00

---

PC Close Date & Time

03 SEP 2020 11:59

---



US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:55:08

---

**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

04 SEP 2020 00:43

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:55:08

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 23:12

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:55:08

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

05 SEP 2020 23:50

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:55:08

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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

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 21:55

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 22:09

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 13:31

PC Open Date & Time

01 SEP 2020 13:07

PC Close Date & Time

01 SEP 2020 15:37

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 22:03

PC Open Date & Time

01 SEP 2020 16:32

PC Close Date & Time

02 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 23:02

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59



US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:55:08

**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

04 SEP 2020 00:45

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 23:14

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 23:51

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 21:56

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 22:10

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:55:08

**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 ☐

US3292023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:55:08

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 13:32
PC Open Date & Time	01 SEP 2020 13:07
PC Close Date & Time	01 SEP 2020 15:37

US3292023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:55:08

**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 ☐



US3292023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:55:08

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 22:05
PC Open Date & Time	01 SEP 2020 16:32
PC Close Date & Time	02 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:55:08

**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 ☒

US3292023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:55:08

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 23:05
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:55:08

**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 ☒

US3292023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:55:08

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 00:46
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:55:08

**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 ☒

US3292023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:55:08

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 23:16
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:55:08

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 ☒



US3292023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:55:08

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 23:52
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:55:08

**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 ☒

US3292023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:55:08

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 21:57
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3292023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:55:08

**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 ☒

US3292023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:55:08

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 22:11
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3292023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:08

Was Contact Attempted?

Yes ☒

No ☐

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

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292023

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:08

Was Contact Attempted?

Yes ☒

No ☐

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

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3292023

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:08

Was Contact Attempted?

Yes ☒

No ☐

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

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292023

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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	VISIT3

US3292023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:08

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	29 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	13:59 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 13:59
Temperature ( <i>xxx.x</i> )	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	80 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3292023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:08

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.*

US3292023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	29 SEP 2020
Collection time ( <i>00:00-23:59</i> )	14:29 (24 HR)
Collection date and time (derived)	29 SEP 2020 14:29

US3292023

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 OCT 2020 14:42:44

Patient Cloud Open Date & Time

04 OCT 2020 00:01

Patient Cloud Close Date & Time

08 OCT 2020 23:59

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**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 14 OCT 2020 11:30:39

Patient Cloud Open Date & Time 11 OCT 2020 00:01

Patient Cloud Close Date & Time 15 OCT 2020 23:59

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**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

20 OCT 2020 14:30:50

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 NOV 2020 16:05:04

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 05:18:39

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 106

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

17 NOV 2020 17:50:15

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 113

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

24 NOV 2020 10:47:39

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>



**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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05 OCT 2020 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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12 OCT 2020 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2020 23:59

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2020 23:59

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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



**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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02 NOV 2020 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

09 NOV 2020 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 NOV 2020 23:59

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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23 NOV 2020 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>



**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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30 NOV 2020 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this 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>	03 DEC 2020 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	07 DEC 2020 23:59
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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 DEC 2020 23:59

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**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 ☐

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 DEC 2020 23:59

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>



**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Open Date & Time](#)

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24 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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28 DEC 2020 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 152

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

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

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

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

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

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

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

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Open Date & Time](#)

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31 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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04 JAN 2021 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Open Date & Time](#)

07 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 173

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

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

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

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

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

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

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

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



**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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25 JAN 2021 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Open Date & Time](#)

28 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**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 ☐

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>



**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

22 FEB 2021 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

TIMEPOINT

DAY 208

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

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

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

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

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

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

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

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Open Date & Time](#)

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25 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 MAR 2021 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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08 MAR 2021 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**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 ☐

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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15 MAR 2021 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**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 ☐  
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 ☐



**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 250

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

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

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

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

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

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

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

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	08 APR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 APR 2021 23:59

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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



**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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26 APR 2021 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**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 ☐

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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03 MAY 2021 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Open Date & Time](#)

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06 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAY 2021 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>



**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

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

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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24 MAY 2021 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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31 MAY 2021 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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 ☐

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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07 JUN 2021 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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



**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Open Date & Time](#)

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10 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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14 JUN 2021 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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21 JUN 2021 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

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

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>



**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 348

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

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

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

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

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

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

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

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**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 ☐

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**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 ☐



**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

TIMEPOINT

DAY 376

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

No ☐  
Yes ☐

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

No ☐  
Yes ☐

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

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

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

No ☐  
Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

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

No ☐  
Yes ☐

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this 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>	19 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	23 AUG 2021 23:59
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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**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 ☐  
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 ☐

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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 ☐



**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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06 SEP 2021 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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13 SEP 2021 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**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 ☐

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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27 SEP 2021 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>



**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 OCT 2021 23:59

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**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 ☐

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

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

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**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 ☐



**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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01 NOV 2021 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

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

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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



**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Open Date & Time](#)

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25 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 NOV 2021 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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06 DEC 2021 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

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

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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20 DEC 2021 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**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 ☐



**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**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 ☐ 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 ☐

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**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 ☐

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

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

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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17 JAN 2022 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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 ☐



**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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20 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 JAN 2022 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

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

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 JAN 2022 23:59

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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°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 ☐

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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 ☐

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**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 ☐



**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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17 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 FEB 2022 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Open Date & Time](#)

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24 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 FEB 2022 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**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 ☐

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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03 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 MAR 2022 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

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

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



**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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21 MAR 2022 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 MAR 2022 23:59

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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 ☐  
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 ☐

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Open Date & Time](#)

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31 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 APR 2022 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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11 APR 2022 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>



**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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18 APR 2022 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

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

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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02 MAY 2022 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

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

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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09 MAY 2022 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>



**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Open Date & Time](#)

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12 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2022 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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23 MAY 2022 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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30 MAY 2022 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 JUN 2022 23:59

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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



**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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13 JUN 2022 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

TIMEPOINT

DAY 684

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

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

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

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

No ☐

Yes ☐

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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20 JUN 2022 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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 ☐  
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 ☐

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 JUL 2022 23:59

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>



**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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11 JUL 2022 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**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 ☐  
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 ☐

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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01 AUG 2022 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**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 ☐  
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 ☐



**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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"/>

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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15 AUG 2022 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**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 ☐  
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 ☐

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Open Date & Time](#)

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18 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 AUG 2022 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

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

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Open Date & Time](#)

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25 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 AUG 2022 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 761

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

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

No ☐

Yes ☐

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

Fever (Temperature  $\geq$  100.4°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 ☐



**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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05 SEP 2022 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

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

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

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**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 ☐

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

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

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



**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

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

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[Patient Cloud Close Date & Time](#)

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03 OCT 2022 23:59

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US3292023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3292023**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 OCT 2022 23:59

US3292023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:08

Was Contact Attempted?

Yes ☒

No ☐

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

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292023

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3292023**

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

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:08**

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*

**US3292023**

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

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:08**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3292023**

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

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 10:55:08**

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"/>



**US3292023**

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

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

**Generated On: 26 Nov 2020 10:55:08**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3292023

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:55:08

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:08

AEID	USA-US072-2020-MRNA-1273-P30 1000007
Adverse event	DIABETIC KETOACIDOSIS
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)	22 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	26 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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)	22 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	26 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

v6.020 DTW (1102) 362 of 2130

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:08

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

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:08

PATIENT CONTACTED STAFF  
TODAY, 27OCT2020, TO STATE  
THAT HE HAD BEEN  
HOSPITALIZED RECENTLY DUE  
TO DIABETIC KETOACIDOSIS.

ON THURSDAY, 22OCT2020,  
PATIENT STATES THAT HE WAS  
NOT FEELING WELL DUE TO AN  
INSULIN PUMP THAT WAS NOT  
FUNCTIONING CORRECTLY. HE

STATES THAT HE HAD BEEN  
WAITING FOR A REPLACEMENT

THAT WAS OVERDUE FOR  
DELIVERY. PATIENT STATES  
THAT HE HAD CHECKED HIS  
BLOOD SUGAR, WHICH HAD  
BEEN REGISTERING BETWEEN  
500 AND 700. THE LOWEST  
READING REGISTERED AT 468.

AFTER REALIZING THAT HIS  
LEVELS WOULD NOT DROP TO  
NORMAL LEVELS, HE

CONTACTED EMS AND WAS  
TRANSPORTED TO A LOCAL  
HOSPITAL. UPON BEING

EVALUATED BY ER  
PHYSICIANS, THE PATIENT  
WAS STARTED ON AN INSULIN  
DRIP. THE PATIENT WAS NOT

ABLE TO REMEMBER ANY  
OTHER MEDICATIONS THAT HE  
MAY HAVE BEEN GIVEN.

PATIENT WAS DISCHARGED IN  
STABLE CONDITION ON  
26OCT2020. MEDICAL RECORDS

WILL BE REQUESTED AS SOON  
AS POSSIBLE. NO FURTHER  
INFORMATION AVAILABLE AT

THIS TIME.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:55:08

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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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US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:08

Name of Medication	VITAMIN B12
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	PREVENTATIVE
Dose per administration	50
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	MCG
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"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:08

	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 2016
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"/>



US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:08

Name of Medication	VITAMIN C
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	SUPPLEMENT
Dose per administration	1500
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"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:08

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 2016
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"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:08

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

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:08

	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 2017	
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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:08

Name of Medication	GABAPENTIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DIABETIC PERIPHERAL NEUROPATHY
Dose per administration	300
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 checked="" 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"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:08

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2013
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:08

Name of Medication	HUMALOG
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	TYPE 1 DIABETES
Dose per administration	100
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 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 checked="" type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input checked="" type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:08

	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) <input type="text"/>		
<hr/>		
Start date completely unknown		True
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"/>		
<hr/>		
Interval Dosage Unit Number (derived) <input type="text"/>		
<hr/>		
Interval Dosage Definition (derived)		802 <input type="radio"/>
		803 <input type="radio"/>
		804 <input type="radio"/>



US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:08

Name of Medication	LEVOTHYROXINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPOTHYROID
Dose per administration	175
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"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:08

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:08

Name of Medication	LISINOPRIL
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	KIDNEY DISEASE PREVENTION
Dose per administration	20
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:08

	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"/>	

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:08

Name of Medication	COMBIGAN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	BILATERAL GLAUCOMA
Dose per administration	3
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input checked="" type="checkbox"/>
If dose unit is Other, specify	DROPS
Frequency	once daily <input type="checkbox"/> twice daily <input checked="" type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:08

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 checked="" type="checkbox"/>
If route of administration is Other, specify	OPHTHALMIC
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input checked="" type="checkbox"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:08

Name of Medication	ROCKLATAN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	BILATERAL GLAUCOMA
Dose per administration	3
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input checked="" type="checkbox"/>
If dose unit is Other, specify	DROPS
Frequency	once daily <input type="checkbox"/> twice daily <input checked="" type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:08

	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 checked="" type="checkbox"/>
If route of administration is Other, specify	OPHTHALMIC	
Start date (dd MMM yyyy)	UN UNK 2007	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:08

Name of Medication LATANOPROST 0.005%

Prophylaxis Yes ☐  
No ☒

Indication BILATERAL GLAUCOMA

Dose per administration 2

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify DROPS

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐  
Intramuscular ☐

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:08

	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 checked="" type="checkbox"/>
If route of administration is Other, specify	OPHTHALMIC	
Start date (dd MMM yyyy)	UN UNK 2007	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:08

Name of Medication	TRAMADOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	LEFT KNEE PAIN
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"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:08

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2007	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:08

Name of Medication	ERGOCALCIFEROL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	VITAMIN D DEFICIENCY
Dose per administration	1.25
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 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 checked="" 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"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:08

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" type="radio"/>
	804	<input type="radio"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:08

Name of Medication	DOXYCYCLINE
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	DENTAL INFECTION
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 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"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:08

	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 2016
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"/>



US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:08

Name of Medication	TRIAMCINOLONE 0.025%
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	FACIAL ATOPIC DERMATITIS
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	APPLICATION
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input checked="" type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:08

	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 2009
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"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:55:08

Name of Medication	GLUCOSE TABLETS
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	TYPE 1 DIABETES
Dose per administration	4
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input checked="" type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:55:08

	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 <hr/>		
Start date (dd MMM yyyy)	UN	UNK 1999
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	<hr/>	
Interval Dosage Unit Number (derived)	<hr/>	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:08

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	INFLUENZA
Dose per administration	.5
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input checked="" type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input checked="" type="radio"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:08

	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)		23 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:55:08

Name of Medication	DEXTROSE 5% IN WATER
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	DIABETIC KETOACIDOSIS
Dose per administration	1000
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input checked="" type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:55:08

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:55:08

Name of Medication INSULIN REGULAR 100 UNITS +  
SODIUM CHLORIDE 0.9%

Prophylaxis Yes ☐  
No ☒

Indication DIABETIC KETOACIDOSIS

Dose per administration 100

Dose unit mg ☐  
ug ☐  
mL ☒  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:55:08

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		22 OCT 2020
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"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:55:08

Name of Medication	INSULIN REGULAR HUMAN RECOMB 100 UNITS/ML
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DIABETIC KETOACIDOSIS
Dose per administration	UNK
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	UNKNOWN
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:55:08

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
<hr/>		
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		22 OCT 2020
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
<hr/>		
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"/>	

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:55:08

Name of Medication SODIUM CHLORIDE 0.45% +  
SODIUM BICARBONATE 8.4% 50  
MEQ

Prophylaxis Yes ☐  
No ☒

Indication DIABETIC KETOACIDOSIS

Dose per administration 1000

Dose unit mg ☐  
ug ☐  
mL ☒  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:55:08

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		22 OCT 2020
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"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:55:08

Name of Medication	SODIUM CHLORIDE 0.9%
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DIABETIC KETOACIDOSIS
Dose per administration	2000
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input checked="" type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:55:08

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (dd MMM yyyy)		22 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		22 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<hr/>
Interval Dosage Unit Number (derived)		<hr/>
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



**US3292023**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 10:55:08**

---

Were any concomitant procedures performed?

Yes ☐

No ☐

---

**If yes, please complete Concomitant Procedures form.**

---

US3292023

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:55:08

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

US3292023

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:55:08

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 ☐

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:55:08

SAEID	USA-US072-2020-MRNA-1273-P301000007
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

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:55:08

SAEID	USA-US072-2020-MRNA-1273-P301000007
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)	28/OCT/2020 13:21
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

US3292023 (Prod: Clinical Trials of Texas, Inc)

**US3292023**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 10:55:08**

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:00:57
User entered 'US3292023'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:49:09

US3292023

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:55:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nathan Cortez (b) (4) [REDACTED]	04 Aug 2020 21:08:56



US3292023

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:55:08

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '04 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	04 Aug 2020 19:49:10

US3292023

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:55:08

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Nathan Cortez (b) (4)	04 Aug 2020 21:08:56

**US3292023**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:55:08**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	04 Aug 2020 21:08:56

US3292023

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:08

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1940'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	04 Aug 2020 19:49:11

US3292023

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:08

[Age](#)

Audit	User	Time (GMT)
User closed query 'Age does not fit Date of Birth.' (Site from System).	System	06 Aug 2020 18:37:57
User entered '80' reason for change: Data Entry Error	(b) (4), (b) (6) [REDACTED]	06 Aug 2020 18:37:57
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	06 Aug 2020 18:32:12
User entered '65'	(b) (4), (b) (6) [REDACTED]	06 Aug 2020 18:32:12

**US3292023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:55:08**

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	06 Aug 2020 18:32:12

**US3292023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:55:08**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '80'	System	04 Aug 2020 21:09:15

**US3292023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:55:08**

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Aug 2020 18:37:57
User entered 'Female (F)'	(b) (4), (b) (6)	06 Aug 2020 18:32:12



US3292023

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:08

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Aug 2020 18:37:57
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	06 Aug 2020 18:32:12

US3292023

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:08

White

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	06 Aug 2020 18:32:12

**US3292023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:55:08**

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:32:12

**US3292023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:55:08**

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:32:12

US3292023

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:08

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:32:12

US3292023

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:08

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:32:12

**US3292023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:55:08**

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:32:12

US3292023

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:08

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:32:12



**US3292023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:55:08**

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:32:12

US3292023

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:55:08

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:32:12

US3292023

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:08

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Aug 2020' reason for change: New Information	Antonio Gutierrez (b) (4)	10 Nov 2020 15:59:48
User entered '4 Aug 2020'	Nathan Cortez (b) (4)	04 Aug 2020 21:09:15

**US3292023**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	04 Aug 2020 21:09:15

**US3292023**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered '2020'	System	04 Aug 2020 21:09:15

US3292023

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:08

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	Nathan Cortez (b) (4) [REDACTED]	04 Aug 2020 21:09:15

US3292023

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nathan Cortez (b) (4) [REDACTED]	04 Aug 2020 21:09:15

US3292023

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:08

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	Nathan Cortez (b) (4) [REDACTED]	04 Aug 2020 21:09:15



US3292023

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:08

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Nathan Cortez (b) (4) [REDACTED]	04 Aug 2020 21:09:15

US3292023

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:08

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nathan Cortez (b) (4) [REDACTED]	04 Aug 2020 21:09:15

US3292023

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:55:08

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	04 Aug 2020 19:49:10

**US3292023**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:55:08**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:09:23

US3292023

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:55:08

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nathan Cortez (b) (4)	04 Aug 2020 21:09:23

US3292023

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:55:08

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 18:43:40

US3292023

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:08

Condition

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: Therapeutic and nontherapeutic effects (excl toxicity), HLT: Therapeutic and nontherapeutic responses, PT: Drug intolerance, LLT: Drug intolerance - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 07:56:13
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 07:56:13
Data point term sent to Coder	System	06 Aug 2020 18:49:19
User entered 'Intolerant to Aricept'	(b) (4), (b) (6) (b) (4)	06 Aug 2020 18:49:00

US3292023

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:08

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

Audit	User	Time (GMT)
User entered 'un UNK 2013'	(b) (4), (b) (6)	06 Aug 2020 18:49:00



US3292023

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:49:00

US3292023

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 18:49:00

**US3292023**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:49:00

US3292023

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:55:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:49:00

**US3292023**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	06 Aug 2020 18:49:00

**US3292023**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered '2013'	System	06 Aug 2020 18:49:00

**US3292023**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 18:49:00

**US3292023**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 18:49:00



US3292023

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:08

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 14:31:03
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 14:31:03
Data point term sent to Coder	System	06 Aug 2020 18:51:26
User entered 'Seasonal allergy: mountain cedar'	(b) (4), (b) (6) (b) (4)	06 Aug 2020 18:51:22

**US3292023**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'un UNK 1990'	(b) (4), (b) (6)	06 Aug 2020 18:51:22

**US3292023**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:51:22

US3292023

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:55:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 18:51:22

**US3292023**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:51:22

**US3292023**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:51:22

**US3292023**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	06 Aug 2020 18:51:22

**US3292023**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered '1990'	System	06 Aug 2020 18:51:22



**US3292023**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 18:51:22

**US3292023**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 18:51:22

US3292023

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:55:08

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Mycotic allergy, LLT: Allergy to molds - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 22:42:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 22:42:43
Data point term sent to Coder	System	06 Aug 2020 18:52:28
User entered 'Seasonal allergy: mold'	(b) (4), (b) (6) (b) (4)	06 Aug 2020 18:51:53

**US3292023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'un UNK 1990'	(b) (4), (b) (6)	06 Aug 2020 18:51:53

**US3292023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:51:53

**US3292023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:55:08**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 18:51:53

**US3292023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:51:53

**US3292023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:51:53



**US3292023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	06 Aug 2020 18:51:53

**US3292023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered '1990'	System	06 Aug 2020 18:51:53

**US3292023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 18:51:53

**US3292023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 18:51:53

US3292023

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:08

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, LLT: Appendectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 18:58:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 18:58:20
Data point term sent to Coder	System	06 Aug 2020 18:57:42
User entered 'Appendectomy'	(b) (4), (b) (6) (b) (4)	06 Aug 2020 18:57:11

US3292023

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:08

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

Audit	User	Time (GMT)
User entered 'un UNK 1958'	(b) (4), (b) (6)	06 Aug 2020 18:57:11

US3292023

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:57:11

US3292023

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 18:57:11



US3292023

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:55:08

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

Audit	User	Time (GMT)
User entered 'un UNK 1958'	(b) (4), (b) (6)	06 Aug 2020 18:57:11

**US3292023**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:57:11

**US3292023**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'Jan 1958'	System	06 Aug 2020 18:57:11

**US3292023**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered '1958'	System	06 Aug 2020 18:57:11

**US3292023**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'Jan 1958'	System	06 Aug 2020 18:57:11

**US3292023**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered '1958'	System	06 Aug 2020 18:57:11

US3292023

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:08

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 18:59:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 18:59:14
Data point term sent to Coder	System	06 Aug 2020 18:58:43
User entered 'Appendicitis'	(b) (4), (b) (6) (b) (4)	06 Aug 2020 18:58:11

**US3292023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'un UNK 1958'	(b) (4), (b) (6)	06 Aug 2020 18:58:11



US3292023

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:58:11

US3292023

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:55:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 18:58:11

**US3292023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'un UNK 1958'	(b) (4), (b) (6)	06 Aug 2020 18:58:11

**US3292023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:58:11

**US3292023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'Jan 1958'	System	06 Aug 2020 18:58:11

**US3292023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered '1958'	System	06 Aug 2020 18:58:11

**US3292023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'Jan 1958'	System	06 Aug 2020 18:58:11

**US3292023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered '1958'	System	06 Aug 2020 18:58:11



US3292023

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:08

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 19:01:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 19:01:25
Data point term sent to Coder	System	06 Aug 2020 19:00:47
User entered 'Tonsilitis'	(b) (4), (b) (6) (b) (4)	06 Aug 2020 18:59:53

US3292023

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:08

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

Audit	User	Time (GMT)
User entered 'un UNK 1946'	(b) (4), (b) (6)	06 Aug 2020 18:59:53

**US3292023**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:59:53

US3292023

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 18:59:53

**US3292023**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'un UNK 1946'	(b) (4), (b) (6)	06 Aug 2020 18:59:53

US3292023

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:55:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:59:53

**US3292023**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'Jan 1946'	System	06 Aug 2020 18:59:53

**US3292023**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered '1946'	System	06 Aug 2020 18:59:53



**US3292023**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'Jan 1946'	System	06 Aug 2020 18:59:53

**US3292023**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered '1946'	System	06 Aug 2020 18:59:53

US3292023

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:08

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 19:03:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 19:03:17
Data point term sent to Coder	System	06 Aug 2020 19:01:48
User entered 'Tonsillectomy'	(b) (4), (b) (6) (b) (4)	06 Aug 2020 19:01:00

US3292023

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:08

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

Audit	User	Time (GMT)
User entered 'un UNK 1946'	(b) (4), (b) (6)	06 Aug 2020 19:01:00

US3292023

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:01:00

US3292023

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:55:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:01:00

**US3292023**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'un UNK 1946'	(b) (4), (b) (6)	06 Aug 2020 19:01:00

**US3292023**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:01:00



**US3292023**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'Jan 1946'	System	06 Aug 2020 19:01:00

**US3292023**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered '1946'	System	06 Aug 2020 19:01:00

**US3292023**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'Jan 1946'	System	06 Aug 2020 19:01:00

**US3292023**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered '1946'	System	06 Aug 2020 19:01:00

US3292023

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:55:08

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 11:37:58
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updatedc' (Site from DM).	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:18:01
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 06:55:33
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee total replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 00:46:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 00:46:27
Data point term sent to Coder	System	06 Aug 2020 19:01:50
User entered 'Knee replacement - left knee'	(b) (4), (b) (6)	06 Aug 2020 19:01:37

**US3292023**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'un UNK 2009'	(b) (4), (b) (6)	06 Aug 2020 19:01:37

**US3292023**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:01:37

**US3292023**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:55:08**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:01:37



**US3292023**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'un UNK 2009'	(b) (4), (b) (6)	06 Aug 2020 19:01:37

US3292023

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:55:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:01:37

**US3292023**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	06 Aug 2020 19:01:37

**US3292023**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered '2009'	System	06 Aug 2020 19:01:37

**US3292023**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	06 Aug 2020 19:01:37

**US3292023**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered '2009'	System	06 Aug 2020 19:01:37

US3292023

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:08

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 11:38:12
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:20:03
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 06:55:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee operation, LLT: Knee operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 00:46:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 00:46:27
Data point term sent to Coder	System	06 Aug 2020 19:02:55
User entered 'Knee surgery - left knee'	(b) (4), (b) (6)	06 Aug 2020 19:02:17

**US3292023**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'un UNK 2007'	(b) (4), (b) (6)	06 Aug 2020 19:02:17



US3292023

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:02:17

US3292023

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:02:17

US3292023

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:55:08

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

Audit	User	Time (GMT)
User entered 'un UNK 2007'	(b) (4), (b) (6)	06 Aug 2020 19:02:17

**US3292023**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:02:17

**US3292023**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	06 Aug 2020 19:02:17

**US3292023**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered '2007'	System	06 Aug 2020 19:02:17

**US3292023**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	06 Aug 2020 19:02:17

**US3292023**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered '2007'	System	06 Aug 2020 19:02:17



US3292023

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:08

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 11:38:24
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal operation, LLT: Back surgery - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 19:22:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	16 Sep 2020 19:22:46
Data point term sent to Coder	System	16 Sep 2020 19:21:23
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	16 Sep 2020 19:21:12
Coding entries removed.	(b) (4)	
User entered 'BACK SURGERY' reason for change: Data Entry Error	Dawn Killian (b) (4)	16 Sep 2020 19:20:52
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 06:55:54
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal operation, LLT: Back surgery - version MedDRA\23.0.	Coder Import (b) (4)	07 Aug 2020 00:36:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	07 Aug 2020 00:36:09
Data point term sent to Coder	System	06 Aug 2020 19:04:58
User entered 'Back surgery (broken)'	(b) (4), (b) (6)	06 Aug 2020 19:03:59

US3292023

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:08

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

Audit	User	Time (GMT)
User entered 'un UNK 1990'	(b) (4), (b) (6)	06 Aug 2020 19:03:59

US3292023

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:03:59

US3292023

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:03:59

US3292023

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:55:08

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

Audit	User	Time (GMT)
User entered 'un UNK 1990'	(b) (4), (b) (6)	06 Aug 2020 19:03:59

**US3292023**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:03:59

**US3292023**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	06 Aug 2020 19:03:59

**US3292023**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered '1990'	System	06 Aug 2020 19:03:59



**US3292023**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	06 Aug 2020 19:03:59

**US3292023**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered '1990'	System	06 Aug 2020 19:03:59

US3292023

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:08

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 11:38:30
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:23:40
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 06:56:08
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Penile therapeutic procedures, PT: Penile operation, LLT: Penile operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 13:20:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 13:20:41
Data point term sent to Coder	System	06 Aug 2020 19:04:59
User entered 'Surgery to penis'	(b) (4), (b) (6)	06 Aug 2020 19:04:47

US3292023

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:08

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

Audit	User	Time (GMT)
User entered 'un UNK 1988'	(b) (4), (b) (6)	06 Aug 2020 19:04:47

US3292023

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:04:47

US3292023

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:55:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:04:47

**US3292023**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'un UNK 1988'	(b) (4), (b) (6)	06 Aug 2020 19:04:47

**US3292023**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:04:47



**US3292023**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'Jan 1988'	System	06 Aug 2020 19:04:47

**US3292023**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered '1988'	System	06 Aug 2020 19:04:47

**US3292023**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'Jan 1988'	System	06 Aug 2020 19:04:47

**US3292023**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered '1988'	System	06 Aug 2020 19:04:47

US3292023

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:55:08

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Renal and urinary tract therapeutic procedures, HLT: Renal therapeutic procedures, PT: Renal stone removal, LLT: Renal stone removal - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:59:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:59:51
Data point term sent to Coder	System	06 Aug 2020 19:06:01
User entered 'Kidney surgery - remove benign spot on kidney'	(b) (4), (b) (6) (b) (4)	06 Aug 2020 19:05:57

US3292023

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:55:08

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

Audit	User	Time (GMT)
User entered 'un UNK 2006'	(b) (4), (b) (6)	06 Aug 2020 19:05:57

**US3292023**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:05:57

**US3292023**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:55:08**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:05:57



US3292023

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:55:08

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

Audit	User	Time (GMT)
User entered 'un UNK 2006'	(b) (4), (b) (6)	06 Aug 2020 19:05:57

**US3292023**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:05:57

**US3292023**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'Jan 2006'	System	06 Aug 2020 19:05:57

**US3292023**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered '2006'	System	06 Aug 2020 19:05:57

**US3292023**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'Jan 2006'	System	06 Aug 2020 19:05:57

**US3292023**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered '2006'	System	06 Aug 2020 19:05:57

US3292023

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:55:08

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 11:39:04
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:24:59
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 06:56:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Stent placement, LLT: Stent placement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 19:08:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 19:08:11
Data point term sent to Coder	System	06 Aug 2020 19:07:06
User entered 'Stent placement'	(b) (4), (b) (6)	06 Aug 2020 19:06:38

US3292023

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:55:08

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

Audit	User	Time (GMT)
User entered 'un UNK 2012'	(b) (4), (b) (6)	06 Aug 2020 19:06:38



**US3292023**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:06:38

US3292023

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:55:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:06:38

**US3292023**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'un UNK 2012'	(b) (4), (b) (6)	06 Aug 2020 19:06:38

**US3292023**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:06:38

**US3292023**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	06 Aug 2020 19:06:38

**US3292023**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered '2012'	System	06 Aug 2020 19:06:38

**US3292023**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	06 Aug 2020 19:06:38

**US3292023**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered '2012'	System	06 Aug 2020 19:06:38



**US3292023**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:55:08**

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	06 Aug 2020 19:08:10
User entered 'Peyronies plaque surgery'	(b) (4), (b) (6)	06 Aug 2020 19:07:28

US3292023

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:55:08

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

Audit	User	Time (GMT)
User entered 'un UNK 1982'	(b) (4), (b) (6)	06 Aug 2020 19:07:28

US3292023

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:55:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:07:28

**US3292023**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:55:08**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:07:28

US3292023

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:55:08

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

Audit	User	Time (GMT)
User entered 'un UNK 1982'	(b) (4), (b) (6)	06 Aug 2020 19:07:28

US3292023

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:55:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:07:28

**US3292023**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'Jan 1982'	System	06 Aug 2020 19:07:28

**US3292023**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered '1982'	System	06 Aug 2020 19:07:28



**US3292023**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'Jan 1982'	System	06 Aug 2020 19:07:28

**US3292023**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered '1982'	System	06 Aug 2020 19:07:28

US3292023

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:55:08

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the condition to include the laterality of Glaucoma (e.g. Left, Right or Bilateral). 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)	29 Sep 2020 11:39:14
User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Glaucoma - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 08:02:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	17 Sep 2020 08:02:02
Data point term sent to Coder	System	16 Sep 2020 19:28:41
Query 'Per DM CLR: Please update the condition to include the laterality of Glaucoma (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	16 Sep 2020 19:28:04
Coding entries removed.	Dawn Killian (b) (4)	16 Sep 2020 19:27:51
User entered 'bilateral GLACOMA' reason for change: Data Entry Error	Dawn Killian (b) (4)	16 Sep 2020 19:27:51
User opened query 'Per DM CLR: Please update the condition to include the laterality of Glaucoma (e.g. Left, Right or Bilateral). 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)	15 Sep 2020 06:56:32
User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Glaucoma - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 19:22:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	18 Aug 2020 19:22:42
Data point term sent to Coder	System	18 Aug 2020 17:52:35
User entered 'glacoma'	Dawn Killian (b) (4)	18 Aug 2020 17:51:53

**US3292023**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'UN UNK 2007'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:51:53

US3292023

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:55:08

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:51:53

US3292023

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:55:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:51:53

**US3292023**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered empty.	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:51:53

US3292023

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:55:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:51:53



**US3292023**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	18 Aug 2020 17:51:53

**US3292023**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered '2007'	System	18 Aug 2020 17:51:53

**US3292023**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 17:51:53

**US3292023**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 17:51:53

US3292023

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:55:08

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 1 diabetes mellitus, LLT: Type I diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 19:22:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 19:22:41
Data point term sent to Coder	System	18 Aug 2020 17:52:35
User entered 'Type I Diabetes'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:52:28

**US3292023**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'UN UNK 1999'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:52:28

**US3292023**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:52:28

US3292023

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:55:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:52:28



**US3292023**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered empty.	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:52:28

US3292023

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:55:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:52:28

**US3292023**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'Jan 1999'	System	18 Aug 2020 17:52:28

**US3292023**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered '1999'	System	18 Aug 2020 17:52:28

**US3292023**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 17:52:28

**US3292023**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 17:52:28

US3292023

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:55:08

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 19:30:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 19:30:48
Data point term sent to Coder	System	18 Aug 2020 17:53:38
User entered 'depression'	Dawn Killian (b) (4)	18 Aug 2020 17:52:48
	(b) (4)	

US3292023

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:55:08

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

Audit	User	Time (GMT)
User entered 'UN UNK 2017'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:52:48



US3292023

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:55:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:52:48

US3292023

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:55:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:52:48

**US3292023**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered empty.	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:52:48

**US3292023**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:52:48

**US3292023**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	18 Aug 2020 17:52:48

**US3292023**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered '2017'	System	18 Aug 2020 17:52:48

**US3292023**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 17:52:48

**US3292023**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 17:52:48



US3292023

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 10:55:08

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the location of Atopic Dermatitis. 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)	29 Sep 2020 11:40:34
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis atopic, LLT: Atopic dermatitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 07:58:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 07:58:51
Data point term sent to Coder	System	16 Sep 2020 19:30:45
Query 'Per DM CLR: Please specify the location of Atopic Dermatitis. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:30:14
Coding entries removed.	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:29:59
User entered 'ATOPIC DERMITIS on face' reason for change: Data Entry Error	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:29:59
User opened query 'Per DM CLR: Please specify the location of Atopic Dermatitis. 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)	15 Sep 2020 06:56:47
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis atopic, LLT: Atopic dermatitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 19:43:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 19:43:37
Data point term sent to Coder	System	18 Aug 2020 17:53:40
User entered 'atopic dermitis'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:53:13

**US3292023**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 26 Nov 2020 10:55:08**

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

Audit	User	Time (GMT)
User entered 'UN UNK 2009'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:53:13

US3292023

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 10:55:08

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:53:13

US3292023

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 10:55:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:53:13

US3292023

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 10:55:08

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

Audit	User	Time (GMT)
User entered empty.	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:53:13

US3292023

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 10:55:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:53:13

**US3292023**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 26 Nov 2020 10:55:08**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	18 Aug 2020 17:53:13

**US3292023**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 26 Nov 2020 10:55:08**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2009'	System	18 Aug 2020 17:53:13



**US3292023**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 17:53:13

**US3292023**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 17:53:13

US3292023

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:55:08

[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)	18 Aug 2020 19:30:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 19:30:47
Data point term sent to Coder	System	18 Aug 2020 17:53:38
User entered 'hypothyroid'	Dawn Killian (b) (4)	18 Aug 2020 17:53:32
	(b) (4)	

US3292023

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:55:08

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:53:32

US3292023

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:55:08

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:53:32

US3292023

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:55:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:53:32

**US3292023**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 26 Nov 2020 10:55:08**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:53:32

US3292023

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 10:55:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:53:32



**US3292023**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 26 Nov 2020 10:55:08**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	18 Aug 2020 17:53:32

**US3292023**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 26 Nov 2020 10:55:08**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2010'	System	18 Aug 2020 17:53:32

**US3292023**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 17:53:32

**US3292023**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 17:53:32

US3292023

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 10:55:08

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic peripheral neuropathy - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 19:30:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 19:30:48
Data point term sent to Coder	System	18 Aug 2020 17:54:41
User entered 'diabetic peripheral neuropathy'	Dawn Killian (b) (4)	18 Aug 2020 17:53:55
	(b) (4)	

**US3292023**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2013'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:53:55

US3292023

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 10:55:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:53:55

US3292023

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 10:55:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:53:55



**US3292023**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 26 Nov 2020 10:55:08**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:53:55

US3292023

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 10:55:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:53:55

**US3292023**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 26 Nov 2020 10:55:08**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	18 Aug 2020 17:53:55

**US3292023**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 26 Nov 2020 10:55:08**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2013'	System	18 Aug 2020 17:53:55

**US3292023**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 17:53:55

**US3292023**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 17:53:55

US3292023

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 10:55:08

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the condition to include the laterality of Knee Pain (e.g. Left, Right or Bilateral). 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)	29 Sep 2020 11:39:52
Query 'Per DM CLR: Please update the condition to include the laterality of Knee Pain (e.g. Left, Right or Bilateral). 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 'cartidge build up added' (Site from DM).	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:26:22
User opened query 'Per DM CLR: Please update the condition to include the laterality of Knee Pain (e.g. Left, Right or Bilateral). 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)	15 Sep 2020 06:56:58
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 19:30:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 19:30:48
Data point term sent to Coder	System	18 Aug 2020 17:54:41
User entered 'knee pain'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:54:30

US3292023

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 10:55:08

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2007'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:54:30



US3292023

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 10:55:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:54:30

**US3292023**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 26 Nov 2020 10:55:08**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:54:30

**US3292023**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 26 Nov 2020 10:55:08**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:54:30

US3292023

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 10:55:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:54:30

**US3292023**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 26 Nov 2020 10:55:08**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	18 Aug 2020 17:54:30

**US3292023**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 26 Nov 2020 10:55:08**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2007'	System	18 Aug 2020 17:54:30

**US3292023**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 17:54:30

**US3292023**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 17:54:30



US3292023

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 10:55:08

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 09:30:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 09:30:21
Data point term sent to Coder	System	18 Aug 2020 17:55:42
User entered 'vitamin d deficiency'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:54:50

US3292023

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 10:55:08

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'Un UNK 2019'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:54:50

US3292023

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 10:55:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:54:50

US3292023

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 10:55:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:54:50

**US3292023**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 26 Nov 2020 10:55:08**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:54:50

US3292023

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 10:55:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Dawn Killian (b) (4) (b) (4)	18 Aug 2020 17:54:50

**US3292023**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 26 Nov 2020 10:55:08**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	18 Aug 2020 17:54:50

**US3292023**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 26 Nov 2020 10:55:08**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2019'	System	18 Aug 2020 17:54:50



**US3292023**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 17:54:50

**US3292023**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 17:54:50

US3292023

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 10:55:08

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Soft tissue therapeutic procedures, HLT: Cartilage therapeutic procedures, PT: Chondroplasty, LLT: Cartilage repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 07:20:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 07:20:44
Data point term sent to Coder	System	16 Sep 2020 19:19:19
User entered 'Bilateral cartilage buildup in knees'	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:18:49

US3292023

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 10:55:08

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2007'	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:18:49

US3292023

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 10:55:08

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:18:49

US3292023

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 10:55:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:18:49

**US3292023**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 26 Nov 2020 10:55:08**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2009'	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:18:49

US3292023

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 10:55:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:18:49



**US3292023**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 26 Nov 2020 10:55:08**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	16 Sep 2020 19:18:49

**US3292023**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 26 Nov 2020 10:55:08**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2007'	System	16 Sep 2020 19:18:49

**US3292023**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	16 Sep 2020 19:18:49

**US3292023**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2009'	System	16 Sep 2020 19:18:49

US3292023

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 10:55:08

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Spinal fractures and dislocations, PT: Spinal fracture, LLT: Spinal fracture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 06:19:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 06:19:59
Data point term sent to Coder	System	16 Sep 2020 19:22:26
User entered 'fractured back'	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:21:44

US3292023

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 10:55:08

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 1990'	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:21:44

US3292023

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 10:55:08

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:21:44

US3292023

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 10:55:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:21:44



**US3292023**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 26 Nov 2020 10:55:08**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 1990'	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:21:44

**US3292023**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:21:44

**US3292023**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 26 Nov 2020 10:55:08**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	16 Sep 2020 19:21:44

**US3292023**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 26 Nov 2020 10:55:08**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1990'	System	16 Sep 2020 19:21:44

**US3292023**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	16 Sep 2020 19:21:44

**US3292023**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1990'	System	16 Sep 2020 19:21:44

US3292023

Folder: Screening

Form: Medical History (25)

Generated On: 26 Nov 2020 10:55:08

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Penile and scrotal disorders (excl infections and inflammations), HLT: Penile disorders NEC (excl erection and ejaculation), PT: Peyronie's disease, LLT: Peyronie's disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 05:45:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 05:45:55
Data point term sent to Coder	System	16 Sep 2020 19:24:32
User entered 'peyronie's plaque'	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:24:11

**US3292023**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 1982'	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:24:11



**US3292023**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:24:11

**US3292023**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 26 Nov 2020 10:55:08**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:24:11

**US3292023**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 26 Nov 2020 10:55:08**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 1988'	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:24:11

**US3292023**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:24:11

**US3292023**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 26 Nov 2020 10:55:08**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1982'	System	16 Sep 2020 19:24:11

**US3292023**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 26 Nov 2020 10:55:08**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1982'	System	16 Sep 2020 19:24:11

**US3292023**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1988'	System	16 Sep 2020 19:24:11

**US3292023**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1988'	System	16 Sep 2020 19:24:11



US3292023

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 10:55:08

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:28:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:28:41
Data point term sent to Coder	System	16 Sep 2020 19:27:38
User entered 'coronary artery disease'	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:26:53

**US3292023**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2012'	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:26:53

US3292023

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 10:55:08

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:26:53

US3292023

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 10:55:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:26:53

**US3292023**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 26 Nov 2020 10:55:08**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:26:53

US3292023

Folder: Screening

Form: Medical History (26)

Generated On: 26 Nov 2020 10:55:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Dawn Killian (b) (4) (b) (4)	16 Sep 2020 19:26:53

**US3292023**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 26 Nov 2020 10:55:08**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	16 Sep 2020 19:26:53

**US3292023**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 26 Nov 2020 10:55:08**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2012'	System	16 Sep 2020 19:26:53



**US3292023**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 19:26:53

**US3292023**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 26 Nov 2020 10:55:08**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 19:26:53

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 18:40:03

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Aug 2020' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	10 Nov 2020 16:00:17
User closed query 'Data is required. Please provide.' (Site from System).	System	06 Aug 2020 18:41:53
User entered '4 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Aug 2020 18:41:53
User opened query 'Data is required. Please provide.' (Site from System).	System	06 Aug 2020 18:40:03
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:40:03

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:08

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Per CDM: According to CRF, a time is required to go along with the date.' (Site from DM).	(b) (4), (b) (6)	17 Aug 2020 14:50:29
Query 'Per CDM: According to CRF, a time is required to go along with the date.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	12 Aug 2020 12:21:15
User entered '14:37' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 12:20:59
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 14:44:17
User opened query 'Per CDM: According to CRF, a time is required to go along with the date.' (Site from DM).	(b) (4), (b) (6)	11 Aug 2020 14:44:16
Query 'Data is required. Please provide.' answered with 'Combined visit.' (Site from System).	(b) (4), (b) (6)	06 Aug 2020 18:40:51
User opened query 'Data is required. Please provide.' System (Site from System).		06 Aug 2020 18:40:03
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:40:03

**US3292023**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:08**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 14:37'	System	10 Nov 2020 16:00:17
User entered '4 Aug 2020 14:37'	System	12 Aug 2020 12:20:59
User entered empty.	System	06 Aug 2020 18:40:03

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:08

Height (xxx.x)

Audit	User	Time (GMT)
User entered '182.1' cm	(b) (4), (b) (6)	06 Aug 2020 18:40:03
DataPoint set to visible.	System	04 Aug 2020 21:09:23

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:08

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '70.5' kg	(b) (4), (b) (6)	06 Aug 2020 18:40:03
DataPoint set to visible.	System	04 Aug 2020 21:09:23



**US3292023**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:08**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Amendment Manager: User entered '21.26029'	System	16 Sep 2020 23:43:05
User entered '21.3'	System	06 Aug 2020 18:40:03
DataPoint set to visible.	System	04 Aug 2020 21:09:23

**US3292023**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:08**

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	06 Aug 2020 18:40:03
DataPoint set to visible.	System	04 Aug 2020 21:09:23

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:08

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please remove the units 'beats/min, breaths/min,mmHg" recorded above ND - 'Not Done' from all the data fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 08:04:38
Query 'Per CDM: Please remove the units 'beats/min, breaths/min,mmHg" recorded above ND - 'Not Done' from all the data fields as appropriate. ' answered with 'these fields can't be removed' (Site from DM).	Dawn Killian (b) (4) (b) (4)	15 Sep 2020 21:47:47
User opened query 'Per CDM: Please remove the units 'beats/min, breaths/min,mmHg" recorded above ND - 'Not Done' from all the data fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 19:49:24
User closed query 'Per CDM: For combined visit, to be marked as 'ND'. ' (Site from DM).	(b) (4), (b) (6)	17 Aug 2020 11:13:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 17:59:36
Query 'Per CDM: For combined visit, to be marked as 'ND'. ' answered with 'ND' (Site from DM).	(b) (4), (b) (6)	13 Aug 2020 15:17:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 14:44:30
User opened query 'Per CDM: For combined visit, to be marked as 'ND'. ' (Site from DM).	(b) (4), (b) (6)	11 Aug 2020 14:44:28
Query 'Data is required. Please provide.' answered with 'Combined visit.' (Site from System).	(b) (4), (b) (6)	06 Aug 2020 18:40:52
User opened query 'Data is required. Please provide.' System (Site from System).		06 Aug 2020 18:40:03
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:40:03

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:08

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: For combined visit, to be marked as 'ND'.' (Site from DM).	(b) (4), (b) (6)	17 Aug 2020 11:13:50
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 23:47:37
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 17:59:36
Query 'Per CDM: For combined visit, to be marked as 'ND'.' answered with 'ND' (Site from DM).	(b) (4), (b) (6)	13 Aug 2020 15:17:08
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 14:44:36
User opened query 'Per CDM: For combined visit, to be marked as 'ND'.' (Site from DM).	(b) (4), (b) (6)	11 Aug 2020 14:44:34
Query 'Data is required. Please provide.' answered with 'Combined visit.' (Site from System).	(b) (4), (b) (6)	06 Aug 2020 18:41:02
User opened query 'Data is required. Please provide.' System (Site from System).		06 Aug 2020 18:40:03
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:40:03

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:08

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 23:47:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 17:59:36
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:40:03

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: For combined visit, to be marked as 'ND'.' (Site from DM).	(b) (4), (b) (6)	17 Aug 2020 11:13:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 17:59:36
Query 'Per CDM: For combined visit, to be marked as 'ND'.' answered with 'ND' (Site from DM).	(b) (4), (b) (6)	13 Aug 2020 15:17:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 14:44:43
User opened query 'Per CDM: For combined visit, to be marked as 'ND'.' (Site from DM).	(b) (4), (b) (6)	11 Aug 2020 14:44:41
Query 'Data is required. Please provide.' answered with 'Combined visit' (Site from System).	(b) (4), (b) (6)	06 Aug 2020 18:41:13
User opened query 'Data is required. Please provide.' System (Site from System).		06 Aug 2020 18:40:03
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:40:03

**US3292023**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:08**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Aug 2020 17:59:36
User entered empty.	System	06 Aug 2020 18:40:03

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: For combined visit, to be marked as 'ND'.' (Site from DM).	(b) (4), (b) (6)	17 Aug 2020 11:13:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 17:59:36
Query 'Per CDM: For combined visit, to be marked as 'ND'.' answered with 'ND' (Site from DM).	(b) (4), (b) (6)	13 Aug 2020 15:17:18
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 14:44:48
User opened query 'Per CDM: For combined visit, to be marked as 'ND'.' (Site from DM).	(b) (4), (b) (6)	11 Aug 2020 14:44:47
Query 'Data is required. Please provide.' answered with 'Combined visit.' (Site from System).	(b) (4), (b) (6)	06 Aug 2020 18:41:19
User opened query 'Data is required. Please provide.' System (Site from System).		06 Aug 2020 18:40:03
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:40:03



**US3292023**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:08**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Aug 2020 17:59:36
User entered empty.	System	06 Aug 2020 18:40:03

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Per CDM: For combined visit, to be marked as 'ND'.' (Site from DM).	(b) (4), (b) (6)	17 Aug 2020 11:13:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 17:59:36
Query 'Per CDM: For combined visit, to be marked as 'ND'.' answered with 'ND' (Site from DM).	(b) (4), (b) (6)	13 Aug 2020 15:17:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 14:44:53
User opened query 'Per CDM: For combined visit, to be marked as 'ND'.' (Site from DM).	(b) (4), (b) (6)	11 Aug 2020 14:44:52
Query 'Data is required. Please provide.' answered with 'Combined visit.' (Site from System).	(b) (4), (b) (6)	06 Aug 2020 18:41:26
User opened query 'Data is required. Please provide.' System (Site from System).		06 Aug 2020 18:40:03
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:40:03

**US3292023**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:08**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Aug 2020 17:59:36
User entered empty.	System	06 Aug 2020 18:40:03

US3292023

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Per CDM: For combined visit, to be marked as 'ND'.' (Site from DM).	(b) (4), (b) (6)	17 Aug 2020 11:14:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 17:59:36
Query 'Per CDM: For combined visit, to be marked as 'ND'.' answered with 'ND' (Site from DM).	(b) (4), (b) (6)	13 Aug 2020 15:17:27
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 14:44:58
User opened query 'Per CDM: For combined visit, to be marked as 'ND'.' (Site from DM).	(b) (4), (b) (6)	11 Aug 2020 14:44:57
Query 'Data is required. Please provide.' answered with 'Combined visit.' (Site from System).	(b) (4), (b) (6)	06 Aug 2020 18:41:47
User opened query 'Data is required. Please provide.' System (Site from System).		06 Aug 2020 18:40:03
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:40:03

**US3292023**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:08**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Aug 2020 17:59:36
User entered empty.	System	06 Aug 2020 18:40:03

US3292023

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 23:47:21
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 18:42:07

US3292023

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '04 Aug 2020' reason for change: New Information	Antonio Gutierrez (b) (4)	10 Nov 2020 16:00:34
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 08:48:07
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	01 Sep 2020 19:07:30
User entered '4 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 23:47:21
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:42:07

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:08

**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)	06 Aug 2020 18:43:21



US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:08

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 18:43:21

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:08

**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)	06 Aug 2020 18:43:21

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:08

**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)	06 Aug 2020 18:43:21

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:08

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 18:43:21

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:08

**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)	06 Aug 2020 18:43:21

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:08

**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)	06 Aug 2020 18:43:21

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:08

**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)	06 Aug 2020 18:43:21

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:08

**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)	06 Aug 2020 18:43:21



US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:08

**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)	06 Aug 2020 18:43:21

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:08

**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)	06 Aug 2020 18:43:21

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:08

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 18:43:21

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:08

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:43:21

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:08

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:43:21

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:08

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:43:21

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:08

**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)	06 Aug 2020 18:43:21

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:08

**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)	06 Aug 2020 18:43:21



US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:08

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)	06 Aug 2020 18:43:21

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:08

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	06 Aug 2020 18:43:21

**US3292023**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 10:55:08**

**Other**

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 18:43:21

US3292023

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:55:08

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:43:21

US3292023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:55:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 19:08:06

US3292023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:55:08

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020' reason for change: New Information	Antonio Gutierrez (b) (4)	10 Nov 2020 15:53:53
User entered '4 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 19:08:06

US3292023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:55:08

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 Aug 2020 19:08:06

**US3292023**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:55:08**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	06 Aug 2020 19:08:06



US3292023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:08

What was the date of randomization? (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	04 Aug 2020 20:49:28

US3292023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:08

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 02:05:27
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:05:27
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Aug 2020 20:49:28
User entered '184711' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	04 Aug 2020 20:49:28

US3292023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:08

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	04 Aug 2020 20:49:28

US3292023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:08

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)	06 Aug 2020 19:10:29

US3292023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:08

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 12:25:34
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:10:29

US3292023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:08

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:10:29

US3292023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:08

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 12:25:53
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:10:29

US3292023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:55:08

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:10:29



US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:55:08

[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 18:00:07
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:55:08

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 18:00:07
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:55:08

[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 18:00:07
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:55:08

[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 18:00:07
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:08

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Aug 2020' reason for change: New Information	Antonio Gutierrez (b) (4)	10 Nov 2020 16:01:20
User entered '4 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:08

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User entered '14:37'	(b) (4), (b) (6)	06 Aug 2020 19:16:56



**US3292023**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 14:37'	System	10 Nov 2020 16:01:20
User entered '4 Aug 2020 14:37'	System	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:08

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	16 Oct 2020 13:26:51
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	Victoria Hernandez (b) (4)	21 Sep 2020 20:19:11
answered with 'NCS' (Site from System).	(b) (4)	
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:43:05
User entered '35.7' C	(b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:08

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:08

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '68'	(b) (4), (b) (6)	06 Aug 2020 19:16:56

**US3292023**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '14'	(b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	06 Aug 2020 19:16:56



US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '126'	(b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '76'	(b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:55:08

[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 18:00:07
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:55:08

[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 18:00:07
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:16:56

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:08

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	06 Aug 2020 19:18:49

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 19:18:49



US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Aug 2020' reason for change: New Information	Antonio Gutierrez (b) (4)	10 Nov 2020 16:01:20
User entered '4 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 19:18:49

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:08

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	14 Aug 2020 14:36:08
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		06 Aug 2020 19:18:49
User entered '16:33'	(b) (4), (b) (6)	06 Aug 2020 19:18:49

**US3292023**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:55:08**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 16:33'	System	10 Nov 2020 16:01:20
User entered '4 Aug 2020 16:33'	System	06 Aug 2020 19:18:49

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:08

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.3' C	(b) (4), (b) (6)	06 Aug 2020 19:18:49

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:08

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	06 Aug 2020 19:18:49

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:08

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:18:49

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '64'	(b) (4), (b) (6)	06 Aug 2020 19:18:49

**US3292023**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:55:08**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	06 Aug 2020 19:18:49



US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	06 Aug 2020 19:18:49

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	06 Aug 2020 19:18:49

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '152'	(b) (4), (b) (6)	06 Aug 2020 19:18:49

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Aug 2020 19:18:49

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '76'	(b) (4), (b) (6)	06 Aug 2020 19:18:49

US3292023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Aug 2020 19:18:49

US3292023

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 23:47:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 19:19:36

US3292023

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:08

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 23:47:56
User entered '4 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 19:19:36



US3292023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nathan Cortez (b) (4) [REDACTED]	04 Aug 2020 21:09:49

US3292023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:08

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Nathan Cortez (b) (4)	04 Aug 2020 21:09:49

US3292023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:08

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty.	Nathan Cortez (b) (4) [REDACTED]	04 Aug 2020 21:09:49

**US3292023**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:55:08**

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	04 Aug 2020 21:09:49

US3292023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '04 Aug 2020' reason for change: New Information	Antonio Gutierrez (b) (4)	10 Nov 2020 16:03:27
User entered '4 Aug 2020'	Nathan Cortez (b) (4)	04 Aug 2020 21:09:49

US3292023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:08

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '16:00'	Nathan Cortez (b) (4) [REDACTED]	04 Aug 2020 21:09:49

**US3292023**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:55:08**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 16:00'	System	10 Nov 2020 16:03:27
User entered '4 Aug 2020 16:00'	System	04 Aug 2020 21:09:49

US3292023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:08

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Nathan Cortez (b) (4)	04 Aug 2020 21:09:49



US3292023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:08

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	04 Aug 2020 21:09:49

US3292023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:55:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	04 Aug 2020 21:09:49

US3292023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 19:20:23

US3292023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Aug 2020' reason for change: New Information	Antonio Gutierrez (b) (4)	10 Nov 2020 16:03:44
User entered '4 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 19:20:23

**US3292023**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:55:08**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '15:00'	(b) (4), (b) (6)	06 Aug 2020 19:20:23

**US3292023**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:55:08**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 15:00'	System	10 Nov 2020 16:03:44
User entered '4 Aug 2020 15:00'	System	06 Aug 2020 19:20:23

US3292023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:55:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Aug 2020' reason for change: New Information	Antonio Gutierrez (b) (4)	10 Nov 2020 16:03:57
User entered '4 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 19:21:04

US3292023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:55:08

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	06 Aug 2020 19:21:04



US3292023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:55:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 19:21:04

US3292023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:55:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '15:25'	(b) (4), (b) (6)	06 Aug 2020 19:21:04

**US3292023**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 15:25'	System	10 Nov 2020 16:03:57
User entered '4 Aug 2020 15:25'	System	06 Aug 2020 19:21:04

US3292023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:55:08

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	06 Aug 2020 19:21:21

US3292023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:55:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Dawn Killian (b) (4)	13 Aug 2020 23:59:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 19:21:21

**US3292023**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:55:08**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Dawn Killian (b) (4)	13 Aug 2020 23:59:45
User entered '15:25'	(b) (4), (b) (6)	06 Aug 2020 19:21:21

**US3292023**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:55:08**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 23:59:45
User entered '4 Aug 2020 15:25'	System	06 Aug 2020 19:21:21

US3292023

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:55:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 19:21:37



**US3292023**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 19:21:37

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:55:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:38:09', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '605c89b0-845a-421c-8871-652c26295ac4'	System	04 Aug 2020 21:39:53
User entered 'Yes (Y)'	System	04 Aug 2020 21:39:53

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:55:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:38:32', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '605c89b0-845a-421c-8871-652c26295ac4' User entered '97.3'	System	04 Aug 2020 21:39:53

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:55:08

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:38:46', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '605c89b0-845a-421c-8871-652c26295ac4'	System	04 Aug 2020 21:39:53
User entered 'No (N)'	System	04 Aug 2020 21:39:53

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:39:49', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '605c89b0-845a-421c-8871-652c26295ac4'	System	04 Aug 2020 21:39:53
User entered '04 Aug 2020 16:39'	System	04 Aug 2020 21:39:53

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 16:20'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 18:50'	System	04 Aug 2020 21:09:49



**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 19:45'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 2'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 3'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:02:19', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0dd1b7da-508c-4e5e-bf87-b0ce13106340'	System	07 Aug 2020 14:02:39
User entered 'Yes (Y)'	System	07 Aug 2020 14:02:39



US3292023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:55:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:01:42', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0dd1b7da-508c-4e5e-bf87-b0ce13106340' User entered '97.3'	System	07 Aug 2020 14:02:39
	System	07 Aug 2020 14:02:39

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:55:08

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:01:55', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0dd1b7da-508c-4e5e-bf87-b0ce13106340'	System	07 Aug 2020 14:02:39
User entered 'No (N)'	System	07 Aug 2020 14:02:39

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:02:35', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0dd1b7da-508c-4e5e-bf87-b0ce13106340'	System	07 Aug 2020 14:02:39
User entered '07 Aug 2020 09:02'	System	07 Aug 2020 14:02:39

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 4'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:55:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T22:11:31', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b81e789c-cba5-418a-adfe-e29d6b9bc431'	System	08 Aug 2020 03:20:44
User entered 'Yes (Y)'	System	08 Aug 2020 03:20:44

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:55:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T22:19:54', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b81e789c-cba5-418a-adfe-e29d6b9bc431' User entered '97.3'	System	08 Aug 2020 03:20:44



US3292023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:55:08

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T22:20:20', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b81e789c-cba5-418a-adfe-e29d6b9bc431'	System	08 Aug 2020 03:20:44
User entered 'No (N)'	System	08 Aug 2020 03:20:44

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T22:20:41', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b81e789c-cba5-418a-adfe-e29d6b9bc431'	System	08 Aug 2020 03:20:44
User entered '07 Aug 2020 22:20'	System	08 Aug 2020 03:20:44

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 5'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:55:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-08T21:42:57', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'bcff659b-396e-4ee8-ab9c-695b0998a285'	System	09 Aug 2020 02:43:26
User entered 'Yes (Y)'	System	09 Aug 2020 02:43:26

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:55:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-08T21:42:27', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'bcff659b-396e-4ee8-ab9c-695b0998a285'	System	09 Aug 2020 02:43:26
User entered '97.4'	System	09 Aug 2020 02:43:26

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:55:08

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-08T21:42:41', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'bcff659b-396e-4ee8-ab9c-695b0998a285'	System	09 Aug 2020 02:43:26
User entered 'No (N)'	System	09 Aug 2020 02:43:26



**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-08T21:43:23', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'bcff659b-396e-4ee8-ab9c-695b0998a285'	System	09 Aug 2020 02:43:26
User entered '08 Aug 2020 21:43'	System	09 Aug 2020 02:43:26

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 6'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:55:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-09T20:44:45', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0283a759-b0e6-48af-8220-925c3b71b38b'	System	10 Aug 2020 01:46:02
User entered 'Yes (Y)'	System	10 Aug 2020 01:46:02

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:55:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-09T20:45:22', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0283a759-b0e6-48af-8220-925c3b71b38b'	System	10 Aug 2020 01:46:02
User entered '96.8'	System	10 Aug 2020 01:46:02

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:55:08

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-09T20:45:40', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0283a759-b0e6-48af-8220-925c3b71b38b'	System	10 Aug 2020 01:46:02
User entered 'No (N)'	System	10 Aug 2020 01:46:02

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-09T20:45:59', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0283a759-b0e6-48af-8220-925c3b71b38b'	System	10 Aug 2020 01:46:02
User entered '09 Aug 2020 20:45'	System	10 Aug 2020 01:46:02



**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 7'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:55:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-10T22:40:43', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'aa5eacfc-e433-4a60-a150-fd5fbb3b823a' User entered 'Yes (Y)'	System	11 Aug 2020 03:41:31
	System	11 Aug 2020 03:41:31

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:55:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-10T22:40:55', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'aa5eacfc-e433-4a60-a150-fd5fbb3b823a' User entered '97.0'	System	11 Aug 2020 03:41:31
	System	11 Aug 2020 03:41:31

US3292023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:55:08

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-10T22:41:07', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'aa5eacfc-e433-4a60-a150-fd5fbb3b823a'	System	11 Aug 2020 03:41:31
User entered 'No (N)'	System	11 Aug 2020 03:41:31

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-10T22:41:27', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'aa5eacfc-e433-4a60-a150-fd5fbb3b823a' User entered '10 Aug 2020 22:41'	System	11 Aug 2020 03:41:31
	System	11 Aug 2020 03:41:31

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 21:09:49



**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:40:20', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '9bb5c30f-ffef-4c2a-9886-478796175963'	System	04 Aug 2020 21:41:46
User entered 'None (1)'	System	04 Aug 2020 21:41:46

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:55:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:40:27', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '9bb5c30f-ffef-4c2a-9886-478796175963'	System	04 Aug 2020 21:41:46
User entered 'No (N)'	System	04 Aug 2020 21:41:46

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:55:08

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:40:44', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '9bb5c30f-ffef-4c2a-9886-478796175963'	System	04 Aug 2020 21:41:46
User entered 'No (N)'	System	04 Aug 2020 21:41:46

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:41:30', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '9bb5c30f-ffef-4c2a-9886-478796175963'	System	04 Aug 2020 21:41:46
User entered 'None (1)'	System	04 Aug 2020 21:41:46

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:41:43', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '9bb5c30f-ffef-4c2a-9886-478796175963'	System	04 Aug 2020 21:41:46
User entered '04 Aug 2020 16:41'	System	04 Aug 2020 21:41:46

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 16:20'	System	04 Aug 2020 21:09:49



**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 18:50'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 19:45'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 2'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 3'	System	04 Aug 2020 21:09:49



US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:04:11', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '1fc8dad2-fb6d-43be-90be-3b6244e8354e'	System	07 Aug 2020 14:05:05
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 14:05:05

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:55:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:04:20', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '1fc8dad2-fb6d-43be-90be-3b6244e8354e'	System	07 Aug 2020 14:05:05
User entered 'No (N)'	System	07 Aug 2020 14:05:05

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:55:08

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:04:26', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '1fc8dad2-fb6d-43be-90be-3b6244e8354e'	System	07 Aug 2020 14:05:05
User entered 'No (N)'	System	07 Aug 2020 14:05:05

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:04:43', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '1fc8dad2-fb6d-43be-90be-3b6244e8354e'	System	07 Aug 2020 14:05:05
User entered 'None (1)'	System	07 Aug 2020 14:05:05

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:05:04', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '1fc8dad2-fb6d-43be-90be-3b6244e8354e'	System	07 Aug 2020 14:05:05
User entered '07 Aug 2020 09:05'	System	07 Aug 2020 14:05:05

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 4'	System	04 Aug 2020 21:09:49



**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 5'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 6'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 21:09:49



**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 7'	System	04 Aug 2020 21:09:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-10T22:41:52', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '92f11b2f-9737-4cb9-8d71-61ed5cb4df0e'	System	11 Aug 2020 03:43:49
User entered 'None (1)'	System	11 Aug 2020 03:43:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:55:08

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-10T22:42:02', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '92f11b2f-9737-4cb9-8d71-61ed5cb4df0e'	System	11 Aug 2020 03:43:49
User entered 'No (N)'	System	11 Aug 2020 03:43:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:55:08

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-10T22:42:11', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '92f11b2f-9737-4cb9-8d71-61ed5cb4df0e'	System	11 Aug 2020 03:43:49
User entered 'No (N)'	System	11 Aug 2020 03:43:49

US3292023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-10T22:42:56', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '92f11b2f-9737-4cb9-8d71-61ed5cb4df0e'	System	11 Aug 2020 03:43:49
User entered 'None (1)'	System	11 Aug 2020 03:43:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-10T22:43:47', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '92f11b2f-9737-4cb9-8d71-61ed5cb4df0e' User entered '10 Aug 2020 22:43'	System	11 Aug 2020 03:43:49
	System	11 Aug 2020 03:43:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 21:09:49



**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:42:13', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4af11f90-2f50-414e-a12f-46bfb1186847'	System	04 Aug 2020 21:43:52
User entered 'None (0)'	System	04 Aug 2020 21:43:52

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:42:19', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4af11f90-2f50-414e-a12f-46bfb1186847'	System	04 Aug 2020 21:43:52
User entered 'None (0)'	System	04 Aug 2020 21:43:52

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:42:31', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4af11f90-2f50-414e-a12f-46bfb1186847'	System	04 Aug 2020 21:43:52
User entered 'None (0)'	System	04 Aug 2020 21:43:52

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:42:38', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4af11f90-2f50-414e-a12f-46bfb1186847'	System	04 Aug 2020 21:43:52
User entered 'None (0)'	System	04 Aug 2020 21:43:52

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:42:47', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4af11f90-2f50-414e-a12f-46bfb1186847'	System	04 Aug 2020 21:43:52
User entered 'None (0)'	System	04 Aug 2020 21:43:52

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:43:01', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4af11f90-2f50-414e-a12f-46bfb1186847'	System	04 Aug 2020 21:43:52
User entered 'None (0)'	System	04 Aug 2020 21:43:52

US3292023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:43:19', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4af11f90-2f50-414e-a12f-46bfb1186847'	System	04 Aug 2020 21:43:52
User entered 'No (N)'	System	04 Aug 2020 21:43:52



**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-04T16:43:49', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4af11f90-2f50-414e-a12f-46bfb1186847'	System	04 Aug 2020 21:43:52
User entered '04 Aug 2020 16:43'	System	04 Aug 2020 21:43:52

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 16:20'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 18:50'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 19:45'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 2'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 21:09:49



**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 3'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:05:28', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7059cf8-d3a4-4c62-97ad-99589d69d72b'	System	07 Aug 2020 14:06:34
User entered 'None (0)'	System	07 Aug 2020 14:06:34

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:05:39', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7059cf8-d3a4-4c62-97ad-99589d69d72b'	System	07 Aug 2020 14:06:34
User entered 'None (0)'	System	07 Aug 2020 14:06:34

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:05:44', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7059cf8-d3a4-4c62-97ad-99589d69d72b'	System	07 Aug 2020 14:06:34
User entered 'None (0)'	System	07 Aug 2020 14:06:34

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:05:49', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7059cf8-d3a4-4c62-97ad-99589d69d72b'	System	07 Aug 2020 14:06:34
User entered 'None (0)'	System	07 Aug 2020 14:06:34

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:06:00', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7059cf8-d3a4-4c62-97ad-99589d69d72b'	System	07 Aug 2020 14:06:34
User entered 'None (0)'	System	07 Aug 2020 14:06:34

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:06:03', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7059cf8-d3a4-4c62-97ad-99589d69d72b'	System	07 Aug 2020 14:06:34
User entered 'None (0)'	System	07 Aug 2020 14:06:34



US3292023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:06:09', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7059cf8-d3a4-4c62-97ad-99589d69d72b'	System	07 Aug 2020 14:06:34
User entered 'No (N)'	System	07 Aug 2020 14:06:34

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T09:06:31', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7059cf8-d3a4-4c62-97ad-99589d69d72b'	System	07 Aug 2020 14:06:34
User entered '07 Aug 2020 09:06'	System	07 Aug 2020 14:06:34

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 4'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T22:20:57', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'ddfc8b3-6c10-4568-9eb3-5daa31e847d3'	System	08 Aug 2020 03:22:33
User entered 'None (0)'	System	08 Aug 2020 03:22:33

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T22:21:05', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'ddfc8b3-6c10-4568-9eb3-5daa31e847d3'	System	08 Aug 2020 03:22:33
User entered 'None (0)'	System	08 Aug 2020 03:22:33

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T22:21:16', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'ddfc8b3-6c10-4568-9eb3-5daa31e847d3'	System	08 Aug 2020 03:22:33
User entered 'None (0)'	System	08 Aug 2020 03:22:33



**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T22:21:20', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'ddfc8b3-6c10-4568-9eb3-5daa31e847d3'	System	08 Aug 2020 03:22:33
User entered 'None (0)'	System	08 Aug 2020 03:22:33

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T22:21:25', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'ddfc8b3-6c10-4568-9eb3-5daa31e847d3'	System	08 Aug 2020 03:22:33
User entered 'None (0)'	System	08 Aug 2020 03:22:33

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T22:21:29', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'ddfc8b3-6c10-4568-9eb3-5daa31e847d3'	System	08 Aug 2020 03:22:33
User entered 'None (0)'	System	08 Aug 2020 03:22:33

US3292023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T22:21:42', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'ddfc8b3-6c10-4568-9eb3-5daa31e847d3'	System	08 Aug 2020 03:22:33
User entered 'No (N)'	System	08 Aug 2020 03:22:33

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-07T22:22:31', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'ddfc8b3-6c10-4568-9eb3-5daa31e847d3'	System	08 Aug 2020 03:22:33
User entered '07 Aug 2020 22:22'	System	08 Aug 2020 03:22:33

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 5'	System	04 Aug 2020 21:09:49



**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-08T21:43:35', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'be7b6fb5-1a8a-4a76-adcd-56192b995923'	System	09 Aug 2020 02:45:42
User entered 'None (0)'	System	09 Aug 2020 02:45:42

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-08T21:43:44', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'be7b6fb5-1a8a-4a76-adcd-56192b995923'	System	09 Aug 2020 02:45:42
User entered 'None (0)'	System	09 Aug 2020 02:45:42

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-08T21:43:50', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'be7b6fb5-1a8a-4a76-adcd-56192b995923'	System	09 Aug 2020 02:45:42
User entered 'None (0)'	System	09 Aug 2020 02:45:42

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-08T21:43:56', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'be7b6fb5-1a8a-4a76-adcd-56192b995923'	System	09 Aug 2020 02:45:42
User entered 'None (0)'	System	09 Aug 2020 02:45:42

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-08T21:44:03', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'be7b6fb5-1a8a-4a76-adcd-56192b995923'	System	09 Aug 2020 02:45:42
User entered 'None (0)'	System	09 Aug 2020 02:45:42

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-08T21:44:09', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'be7b6fb5-1a8a-4a76-adcd-56192b995923'	System	09 Aug 2020 02:45:42
User entered 'None (0)'	System	09 Aug 2020 02:45:42

US3292023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-08T21:44:36', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'be7b6fb5-1a8a-4a76-adcd-56192b995923'	System	09 Aug 2020 02:45:42
User entered 'No (N)'	System	09 Aug 2020 02:45:42

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-08T21:45:40', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'be7b6fb5-1a8a-4a76-adcd-56192b995923'	System	09 Aug 2020 02:45:42
User entered '08 Aug 2020 21:45'	System	09 Aug 2020 02:45:42



**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 6'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-09T20:46:32', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4afff1b9-fcec-4b75-88e4-a19533a82c42'	System	10 Aug 2020 01:48:40
User entered 'None (0)'	System	10 Aug 2020 01:48:40

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-09T20:46:43', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4afff1b9-fcec-4b75-88e4-a19533a82c42'	System	10 Aug 2020 01:48:40
User entered 'None (0)'	System	10 Aug 2020 01:48:40

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-09T20:46:50', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4afff1b9-fcec-4b75-88e4-a19533a82c42'	System	10 Aug 2020 01:48:40
User entered 'None (0)'	System	10 Aug 2020 01:48:40

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-09T20:46:57', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4afff1b9-fcec-4b75-88e4-a19533a82c42'	System	10 Aug 2020 01:48:40
User entered 'None (0)'	System	10 Aug 2020 01:48:40

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-09T20:47:07', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4afff1b9-fcec-4b75-88e4-a19533a82c42'	System	10 Aug 2020 01:48:40
User entered 'None (0)'	System	10 Aug 2020 01:48:40



**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-09T20:47:12', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4afff1b9-fcec-4b75-88e4-a19533a82c42'	System	10 Aug 2020 01:48:40
User entered 'None (0)'	System	10 Aug 2020 01:48:40

US3292023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-09T20:47:21', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4afff1b9-fcec-4b75-88e4-a19533a82c42'	System	10 Aug 2020 01:48:40
User entered 'No (N)'	System	10 Aug 2020 01:48:40

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-08-09T20:48:34', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '4afff1b9-fcec-4b75-88e4-a19533a82c42'	System	10 Aug 2020 01:48:40
User entered '09 Aug 2020 20:48'	System	10 Aug 2020 01:48:40

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 7'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 21:09:49



US3292023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	13 Aug 2020 16:15:30

US3292023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Dawn Killian (b) (4) (b) (4)	13 Aug 2020 16:15:30

US3292023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:08

[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)	13 Aug 2020 16:15:30

**US3292023**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Dawn Killian (b) (4) (b) (4)	13 Aug 2020 16:15:30

US3292023

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	13 Aug 2020 16:15:37

**US3292023**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Aug 2020 16:15:37

US3292023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	20 Aug 2020 00:16:58

**US3292023**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:08**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Aug 2020'	Dawn Killian (b) (4) (b) (4)	20 Aug 2020 00:16:58



US3292023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:08

[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)	20 Aug 2020 00:16:58

**US3292023**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Dawn Killian (b) (4) (b) (4)	20 Aug 2020 00:16:58

US3292023

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	20 Aug 2020 00:16:47

**US3292023**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Aug 2020 00:16:47

US3292023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	26 Aug 2020 00:38:50

**US3292023**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:08**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 Aug 2020'	Kristy Trevino (b) (4) (b) (4)	26 Aug 2020 00:38:50

US3292023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:08

[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)	26 Aug 2020 00:38:50

**US3292023**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Kristy Trevino (b) (4) (b) (4)	26 Aug 2020 00:38:50



US3292023

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	26 Aug 2020 00:38:55

**US3292023**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Aug 2020 00:38:55

US3292023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:07:30

US3292023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:08

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '1 Sep 2020'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:07:30

US3292023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:08

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:07:30

**US3292023**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:55:08**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	01 Sep 2020 19:07:30

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:08

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:08:08

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:08

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:08:08



US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Sep 2020'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:08:08

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:08

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User entered '11:55'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:08:08

**US3292023**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '1 Sep 2020 11:55'	System	01 Sep 2020 19:08:08

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:08

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.2' C	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:08:08

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:08

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:08:08

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:08

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:08:08

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '70'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:08:08

**US3292023**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Sep 2020 19:08:08



US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '12'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:08:08

**US3292023**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Sep 2020 19:08:08

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '132'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:08:08

**US3292023**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 19:08:08

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:55:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '76'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:08:08

**US3292023**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 19:08:08

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:08

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:08:49

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:08

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:08:49



US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Sep 2020'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:08:49

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:08

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User entered '13:26'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:08:49

**US3292023**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:55:08**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '1 Sep 2020 13:26'	System	01 Sep 2020 19:08:49

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:08

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:08:49

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:08

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:08:49

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:08

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:08:49

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '62'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:08:49

**US3292023**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:55:08**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Sep 2020 19:08:49



US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:08:49

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Sep 2020 19:08:49

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '139'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:08:49

**US3292023**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:55:08**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 19:08:49

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '74'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:08:49

US3292023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:55:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Sep 2020 19:08:49

US3292023

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:08

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:09:00

US3292023

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:08

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Sep 2020'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:09:00



US3292023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nathan Cortez (b) (4) [REDACTED]	01 Sep 2020 17:50:59

US3292023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:08

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Nathan Cortez (b) (4) [REDACTED]	01 Sep 2020 17:50:59

US3292023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:08

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty.	Nathan Cortez (b) (4) [REDACTED]	01 Sep 2020 17:50:59

**US3292023**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:55:08**

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 17:50:59

US3292023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '1 Sep 2020'	Nathan Cortez (b) (4)	01 Sep 2020 17:50:59

US3292023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:08

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:47'	Nathan Cortez (b) (4) [REDACTED]	01 Sep 2020 17:50:59

**US3292023**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:55:08**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '1 Sep 2020 12:47'	System	01 Sep 2020 17:50:59

US3292023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:08

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Nathan Cortez (b) (4)	01 Sep 2020 17:50:59



US3292023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:08

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	01 Sep 2020 17:50:59

US3292023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:55:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 17:50:59

US3292023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:09:14

US3292023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Sep 2020'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:09:14

US3292023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '12:17'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:09:14

**US3292023**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:55:08**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '1 Sep 2020 12:17'	System	01 Sep 2020 19:09:14

US3292023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:55:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Sep 2020'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:09:33

US3292023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:55:08

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:09:33



US3292023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:55:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:09:33

US3292023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:55:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '12:25'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:09:33

**US3292023**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:25'	System	01 Sep 2020 19:09:33

US3292023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:55:08

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:09:33

US3292023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:55:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:09:33

US3292023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:55:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:09:33

**US3292023**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:55:08**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 19:09:33

US3292023

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	01 Sep 2020 19:10:03



**US3292023**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 19:10:03

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:55:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:29:46', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '05a0d4d0-d688-4818-9872-254893835936'	System	01 Sep 2020 18:30:41
User entered 'Yes (Y)'	System	01 Sep 2020 18:30:41

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:55:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:30:07', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '05a0d4d0-d688-4818-9872-254893835936'	System	01 Sep 2020 18:30:41
User entered '98.3'	System	01 Sep 2020 18:30:41

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:55:08

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:30:16', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '05a0d4d0-d688-4818-9872-254893835936'	System	01 Sep 2020 18:30:41
User entered 'No (N)'	System	01 Sep 2020 18:30:41

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:30:38', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '05a0d4d0-d688-4818-9872-254893835936'	System	01 Sep 2020 18:30:41
User entered '01 Sep 2020 13:30'	System	01 Sep 2020 18:30:41

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:55:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 13:07'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 15:37'	System	01 Sep 2020 17:50:59



**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:55:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T21:59:56', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'ee88cf6d-58c6-4955-89fa-940df54263af' User entered 'Yes (Y)'	System	02 Sep 2020 03:01:10

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:55:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:00:16', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'ee88cf6d-58c6-4955-89fa-940df54263af' User entered '98.1'	System	02 Sep 2020 03:01:10

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:55:08

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:00:25', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'ee88cf6d-58c6-4955-89fa-940df54263af'	System	02 Sep 2020 03:01:10
User entered 'No (N)'	System	02 Sep 2020 03:01:10

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:00:57', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'ee88cf6d-58c6-4955-89fa-940df54263af'	System	02 Sep 2020 03:01:10
User entered '01 Sep 2020 22:00'	System	02 Sep 2020 03:01:10

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 16:32'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 2'	System	01 Sep 2020 17:50:59



US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:55:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T22:59:18', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'aba0ead1-8b4d-4201-a104-913bc094c452'	System	03 Sep 2020 04:00:18
User entered 'Yes (Y)'	System	03 Sep 2020 04:00:18

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:55:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T22:59:31', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'aba0ead1-8b4d-4201-a104-913bc094c452'	System	03 Sep 2020 04:00:18
User entered '99.3'	System	03 Sep 2020 04:00:18

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:55:08

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T22:59:47', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'aba0ead1-8b4d-4201-a104-913bc094c452'	System	03 Sep 2020 04:00:18
User entered 'No (N)'	System	03 Sep 2020 04:00:18

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T23:00:13', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'aba0ead1-8b4d-4201-a104-913bc094c452'	System	03 Sep 2020 04:00:18
User entered '02 Sep 2020 23:00'	System	03 Sep 2020 04:00:18

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 3'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:55:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:42:01', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '5cb0eb66-b841-4c70-b485-aff973c8f0ca'	System	04 Sep 2020 05:43:10
User entered 'Yes (Y)'	System	04 Sep 2020 05:43:10



US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:55:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:42:25', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '5cb0eb66-b841-4c70-b485-aff973c8f0ca'	System	04 Sep 2020 05:43:10
User entered '98.2'	System	04 Sep 2020 05:43:10

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:55:08

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:42:46', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '5cb0eb66-b841-4c70-b485-aff973c8f0ca'	System	04 Sep 2020 05:43:10
User entered 'No (N)'	System	04 Sep 2020 05:43:10

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:43:04', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '5cb0eb66-b841-4c70-b485-aff973c8f0ca' User entered '04 Sep 2020 00:43'	System	04 Sep 2020 05:43:10
	System	04 Sep 2020 05:43:10

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 4'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:55:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:11:56', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7415cb8b-d74d-4381-8604-67af80ba3623'	System	05 Sep 2020 04:12:50
User entered 'Yes (Y)'	System	05 Sep 2020 04:12:50

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:55:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:12:22', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7415cb8b-d74d-4381-8604-67af80ba3623'	System	05 Sep 2020 04:12:50
User entered '97.6'	System	05 Sep 2020 04:12:50



US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:55:08

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:12:33', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7415cb8b-d74d-4381-8604-67af80ba3623'	System	05 Sep 2020 04:12:50
User entered 'No (N)'	System	05 Sep 2020 04:12:50

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:12:49', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7415cb8b-d74d-4381-8604-67af80ba3623'	System	05 Sep 2020 04:12:50
User entered '04 Sep 2020 23:12'	System	05 Sep 2020 04:12:50

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 5'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:49:18', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'eae81253-fc6a-4f05-8b5b-808acf63ee72'	System	06 Sep 2020 04:50:15
User entered 'Yes (Y)'	System	06 Sep 2020 04:50:15

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:55:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:49:39', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'eae81253-fc6a-4f05-8b5b-808acf63ee72'	System	06 Sep 2020 04:50:15
User entered '97.2'	System	06 Sep 2020 04:50:15

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:55:08

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:49:53', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'eae81253-fc6a-4f05-8b5b-808acf63ee72'	System	06 Sep 2020 04:50:15
User entered 'No (N)'	System	06 Sep 2020 04:50:15



**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:50:12', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'eae81253-fc6a-4f05-8b5b-808acf63ee72'	System	06 Sep 2020 04:50:15
User entered '05 Sep 2020 23:50'	System	06 Sep 2020 04:50:15

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 6'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:55:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:54:29', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '3634a445-8d43-4965-a37f-b992bc91a9d2'	System	07 Sep 2020 02:55:25
User entered 'Yes (Y)'	System	07 Sep 2020 02:55:25

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:55:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:55:03', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '3634a445-8d43-4965-a37f-b992bc91a9d2'	System	07 Sep 2020 02:55:25
User entered '96.6'	System	07 Sep 2020 02:55:25

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:55:08

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:55:09', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '3634a445-8d43-4965-a37f-b992bc91a9d2'	System	07 Sep 2020 02:55:25
User entered 'No (N)'	System	07 Sep 2020 02:55:25

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:55:21', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '3634a445-8d43-4965-a37f-b992bc91a9d2'	System	07 Sep 2020 02:55:25
User entered '06 Sep 2020 21:55'	System	07 Sep 2020 02:55:25



US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:55:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 7'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:55:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:08:41', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'a4c86b70-b1cd-4762-ba1a-1a6a0f0055ab'	System	08 Sep 2020 03:09:20
User entered 'Yes (Y)'	System	08 Sep 2020 03:09:20

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:55:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:08:52', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'a4c86b70-b1cd-4762-ba1a-1a6a0f0055ab' User entered '97.6'	System	08 Sep 2020 03:09:20

US3292023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:55:08

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:09:00', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'a4c86b70-b1cd-4762-ba1a-1a6a0f0055ab'	System	08 Sep 2020 03:09:20
User entered 'No (N)'	System	08 Sep 2020 03:09:20

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:09:18', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'a4c86b70-b1cd-4762-ba1a-1a6a0f0055ab' User entered '07 Sep 2020 22:09'	System	08 Sep 2020 03:09:20
	System	08 Sep 2020 03:09:20

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 17:50:59



**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:30:53', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '2ec4c6f1-402b-43cb-a630-dbc3d33ca31e'	System	01 Sep 2020 18:31:30
User entered 'None (1)'	System	01 Sep 2020 18:31:30

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:55:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:31:03', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '2ec4c6f1-402b-43cb-a630-dbc3d33ca31e'	System	01 Sep 2020 18:31:30
User entered 'No (N)'	System	01 Sep 2020 18:31:30

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:55:08

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:31:10', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '2ec4c6f1-402b-43cb-a630-dbc3d33ca31e'	System	01 Sep 2020 18:31:30
User entered 'No (N)'	System	01 Sep 2020 18:31:30

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:31:19', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '2ec4c6f1-402b-43cb-a630-dbc3d33ca31e' User entered 'None (1)'	System	01 Sep 2020 18:31:30
	System	01 Sep 2020 18:31:30

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:31:28', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '2ec4c6f1-402b-43cb-a630-dbc3d33ca31e'	System	01 Sep 2020 18:31:30
User entered '01 Sep 2020 13:31'	System	01 Sep 2020 18:31:30

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 13:07'	System	01 Sep 2020 17:50:59



**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 15:37'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:01:58', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '3b293068-21a6-4b85-af23-8349e4494ebd'	System	02 Sep 2020 03:03:08
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 03:03:08

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:55:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:02:05', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '3b293068-21a6-4b85-af23-8349e4494ebd'	System	02 Sep 2020 03:03:08
User entered 'No (N)'	System	02 Sep 2020 03:03:08

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:55:08

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:02:25', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '3b293068-21a6-4b85-af23-8349e4494ebd'	System	02 Sep 2020 03:03:08
User entered 'No (N)'	System	02 Sep 2020 03:03:08

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:02:35', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '3b293068-21a6-4b85-af23-8349e4494ebd' User entered 'None (1)'	System	02 Sep 2020 03:03:08
	System	02 Sep 2020 03:03:08

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:03:06', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '3b293068-21a6-4b85-af23-8349e4494ebd'	System	02 Sep 2020 03:03:08
User entered '01 Sep 2020 22:03'	System	02 Sep 2020 03:03:08

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 16:32'	System	01 Sep 2020 17:50:59



**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 2'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T23:00:48', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b4376431-5343-461a-914d-413d49227ae3'	System	03 Sep 2020 04:02:07
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 04:02:07

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:55:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T23:01:03', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b4376431-5343-461a-914d-413d49227ae3'	System	03 Sep 2020 04:02:07
User entered 'No (N)'	System	03 Sep 2020 04:02:07

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:55:08

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T23:01:15', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b4376431-5343-461a-914d-413d49227ae3'	System	03 Sep 2020 04:02:07
User entered 'No (N)'	System	03 Sep 2020 04:02:07

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T23:01:31', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b4376431-5343-461a-914d-413d49227ae3'	System	03 Sep 2020 04:02:07
User entered 'None (1)'	System	03 Sep 2020 04:02:07

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T23:02:05', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b4376431-5343-461a-914d-413d49227ae3'	System	03 Sep 2020 04:02:07
User entered '02 Sep 2020 23:02'	System	03 Sep 2020 04:02:07

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 17:50:59



**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 3'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:43:32', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7be83de8-e308-48bb-bb14-b1696f2a7ba3'	System	04 Sep 2020 05:45:29
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 05:45:29

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:55:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:43:37', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7be83de8-e308-48bb-bb14-b1696f2a7ba3'	System	04 Sep 2020 05:45:29
User entered 'No (N)'	System	04 Sep 2020 05:45:29

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:55:08

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:45:16', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7be83de8-e308-48bb-bb14-b1696f2a7ba3'	System	04 Sep 2020 05:45:29
User entered 'No (N)'	System	04 Sep 2020 05:45:29

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:44:52', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7be83de8-e308-48bb-bb14-b1696f2a7ba3'	System	04 Sep 2020 05:45:29
User entered 'None (1)'	System	04 Sep 2020 05:45:29

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:45:25', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7be83de8-e308-48bb-bb14-b1696f2a7ba3'	System	04 Sep 2020 05:45:29
User entered '04 Sep 2020 00:45'	System	04 Sep 2020 05:45:29

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 17:50:59



**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 4'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:13:22', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '67283d93-e6bc-4f50-acc8-815f86cf8a11'	System	05 Sep 2020 04:14:23
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 04:14:23

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:55:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:13:30', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '67283d93-e6bc-4f50-acc8-815f86cf8a11'	System	05 Sep 2020 04:14:23
User entered 'No (N)'	System	05 Sep 2020 04:14:23

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:55:08

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:13:37', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '67283d93-e6bc-4f50-acc8-815f86cf8a11'	System	05 Sep 2020 04:14:23
User entered 'No (N)'	System	05 Sep 2020 04:14:23

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:13:45', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '67283d93-e6bc-4f50-acc8-815f86cf8a11' User entered 'None (1)'	System	05 Sep 2020 04:14:23
	System	05 Sep 2020 04:14:23

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:14:18', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '67283d93-e6bc-4f50-acc8-815f86cf8a11'	System	05 Sep 2020 04:14:23
User entered '04 Sep 2020 23:14'	System	05 Sep 2020 04:14:23

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 17:50:59



**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 5'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:50:28', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '698839fd-5eae-443b-8821-a94b71f7bf2b'	System	06 Sep 2020 04:51:10
User entered 'None (1)'	System	06 Sep 2020 04:51:10

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:55:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:50:35', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '698839fd-5eae-443b-8821-a94b71f7bf2b'	System	06 Sep 2020 04:51:10
User entered 'No (N)'	System	06 Sep 2020 04:51:10

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:55:08

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:50:41', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '698839fd-5eae-443b-8821-a94b71f7bf2b'	System	06 Sep 2020 04:51:10
User entered 'No (N)'	System	06 Sep 2020 04:51:10

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:50:48', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '698839fd-5eae-443b-8821-a94b71f7bf2b'	System	06 Sep 2020 04:51:10
User entered 'None (1)'	System	06 Sep 2020 04:51:10

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:51:08', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '698839fd-5eae-443b-8821-a94b71f7bf2b'	System	06 Sep 2020 04:51:10
User entered '05 Sep 2020 23:51'	System	06 Sep 2020 04:51:10

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 17:50:59



**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 6'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:55:45', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0826b5d1-3040-48be-8daa-6ad332a7b55a'	System	07 Sep 2020 02:56:32
User entered 'None (1)'	System	07 Sep 2020 02:56:32

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:55:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:55:52', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0826b5d1-3040-48be-8daa-6ad332a7b55a'	System	07 Sep 2020 02:56:32
User entered 'No (N)'	System	07 Sep 2020 02:56:32

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:55:08

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:55:58', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0826b5d1-3040-48be-8daa-6ad332a7b55a'	System	07 Sep 2020 02:56:32
User entered 'No (N)'	System	07 Sep 2020 02:56:32

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:56:05', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0826b5d1-3040-48be-8daa-6ad332a7b55a'	System	07 Sep 2020 02:56:32
User entered 'None (1)'	System	07 Sep 2020 02:56:32

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:56:29', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0826b5d1-3040-48be-8daa-6ad332a7b55a'	System	07 Sep 2020 02:56:32
User entered '06 Sep 2020 21:56'	System	07 Sep 2020 02:56:32

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 17:50:59



**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 7'	System	01 Sep 2020 17:50:59

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:09:30', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '79dc09d3-4fa3-4a9d-ba08-80ce682eeacd'	System	08 Sep 2020 03:10:04
User entered 'None (1)'	System	08 Sep 2020 03:10:04

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:55:08

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:09:35', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '79dc09d3-4fa3-4a9d-ba08-80ce682eeacd'	System	08 Sep 2020 03:10:04
User entered 'No (N)'	System	08 Sep 2020 03:10:04

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:55:08

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:09:40', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '79dc09d3-4fa3-4a9d-ba08-80ce682eeacd'	System	08 Sep 2020 03:10:04
User entered 'No (N)'	System	08 Sep 2020 03:10:04

US3292023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:09:47', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '79dc09d3-4fa3-4a9d-ba08-80ce682eeacd' User entered 'None (1)'	System	08 Sep 2020 03:10:04
	System	08 Sep 2020 03:10:04

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:10:01', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '79dc09d3-4fa3-4a9d-ba08-80ce682eeacd'	System	08 Sep 2020 03:10:04
User entered '07 Sep 2020 22:10'	System	08 Sep 2020 03:10:04

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 17:50:59



**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:31:40', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7854f4a0-b57e-40cd-bc6d-3fb5455dd3e9'	System	01 Sep 2020 18:32:31
User entered 'None (0)'	System	01 Sep 2020 18:32:31

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:31:43', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7854f4a0-b57e-40cd-bc6d-3fb5455dd3e9' User entered 'None (0)'	System	01 Sep 2020 18:32:31
	System	01 Sep 2020 18:32:31

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:31:48', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7854f4a0-b57e-40cd-bc6d-3fb5455dd3e9'	System	01 Sep 2020 18:32:31
User entered 'None (0)'	System	01 Sep 2020 18:32:31

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:31:55', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7854f4a0-b57e-40cd-bc6d-3fb5455dd3e9'	System	01 Sep 2020 18:32:31
User entered 'None (0)'	System	01 Sep 2020 18:32:31

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:31:58', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7854f4a0-b57e-40cd-bc6d-3fb5455dd3e9'	System	01 Sep 2020 18:32:31
User entered 'None (0)'	System	01 Sep 2020 18:32:31

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:32:02', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7854f4a0-b57e-40cd-bc6d-3fb5455dd3e9'	System	01 Sep 2020 18:32:31
User entered 'None (0)'	System	01 Sep 2020 18:32:31



US3292023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:32:13', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7854f4a0-b57e-40cd-bc6d-3fb5455dd3e9'	System	01 Sep 2020 18:32:31
User entered 'No (N)'	System	01 Sep 2020 18:32:31

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T13:32:28', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7854f4a0-b57e-40cd-bc6d-3fb5455dd3e9'	System	01 Sep 2020 18:32:31
User entered '01 Sep 2020 13:32'	System	01 Sep 2020 18:32:31

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 13:07'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 15:37'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:08**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:03:26', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7b574e4-3237-4413-a2b9-056d80f0fae9'	System	02 Sep 2020 03:05:16
User entered 'None (0)'	System	02 Sep 2020 03:05:16

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:08**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:03:33', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7b574e4-3237-4413-a2b9-056d80f0fae9'	System	02 Sep 2020 03:05:16
User entered 'None (0)'	System	02 Sep 2020 03:05:16

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:08**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:03:48', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7b574e4-3237-4413-a2b9-056d80f0fae9'	System	02 Sep 2020 03:05:16
User entered 'None (0)'	System	02 Sep 2020 03:05:16



US3292023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:55:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:03:56', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7b574e4-3237-4413-a2b9-056d80f0fae9'	System	02 Sep 2020 03:05:16
User entered 'None (0)'	System	02 Sep 2020 03:05:16

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:04:01', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7b574e4-3237-4413-a2b9-056d80f0fae9'	System	02 Sep 2020 03:05:16
User entered 'None (0)'	System	02 Sep 2020 03:05:16

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:08**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:04:06', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7b574e4-3237-4413-a2b9-056d80f0fae9'	System	02 Sep 2020 03:05:16
User entered 'None (0)'	System	02 Sep 2020 03:05:16

US3292023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:04:28', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7b574e4-3237-4413-a2b9-056d80f0fae9'	System	02 Sep 2020 03:05:16
User entered 'No (N)'	System	02 Sep 2020 03:05:16

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-01T22:05:11', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'e7b574e4-3237-4413-a2b9-056d80f0fae9'	System	02 Sep 2020 03:05:16
User entered '01 Sep 2020 22:05'	System	02 Sep 2020 03:05:16

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 16:32'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 2'	System	01 Sep 2020 17:50:59



**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:08**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T23:03:51', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '5f19f3e5-ea9d-4273-89a4-d2b4ab54e277'	System	03 Sep 2020 04:05:51
User entered 'None (0)'	System	03 Sep 2020 04:05:51

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:08**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T23:04:10', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '5f19f3e5-ea9d-4273-89a4-d2b4ab54e277'	System	03 Sep 2020 04:05:51
User entered 'None (0)'	System	03 Sep 2020 04:05:51

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:08**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T23:04:19', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '5f19f3e5-ea9d-4273-89a4-d2b4ab54e277'	System	03 Sep 2020 04:05:51
User entered 'None (0)'	System	03 Sep 2020 04:05:51

US3292023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:55:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T23:04:30', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '5f19f3e5-ea9d-4273-89a4-d2b4ab54e277'	System	03 Sep 2020 04:05:51
User entered 'None (0)'	System	03 Sep 2020 04:05:51

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T23:04:41', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '5f19f3e5-ea9d-4273-89a4-d2b4ab54e277'	System	03 Sep 2020 04:05:51
User entered 'None (0)'	System	03 Sep 2020 04:05:51

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:08**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T23:04:46', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '5f19f3e5-ea9d-4273-89a4-d2b4ab54e277'	System	03 Sep 2020 04:05:51
User entered 'None (0)'	System	03 Sep 2020 04:05:51

US3292023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T23:05:05', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '5f19f3e5-ea9d-4273-89a4-d2b4ab54e277'	System	03 Sep 2020 04:05:51
User entered 'No (N)'	System	03 Sep 2020 04:05:51

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-02T23:05:49', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '5f19f3e5-ea9d-4273-89a4-d2b4ab54e277'	System	03 Sep 2020 04:05:51
User entered '02 Sep 2020 23:05'	System	03 Sep 2020 04:05:51



**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 3'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:45:43', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0fcbcbc2-49a3-4e29-b7f9-812ca925811d'	System	04 Sep 2020 05:46:53
User entered 'None (0)'	System	04 Sep 2020 05:46:53

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:45:53', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0fcbcbc2-49a3-4e29-b7f9-812ca925811d' User entered 'None (0)'	System	04 Sep 2020 05:46:53
	System	04 Sep 2020 05:46:53

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:45:58', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0fcbcbc2-49a3-4e29-b7f9-812ca925811d'	System	04 Sep 2020 05:46:53
User entered 'None (0)'	System	04 Sep 2020 05:46:53

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:46:06', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0fcbcbc2-49a3-4e29-b7f9-812ca925811d'	System	04 Sep 2020 05:46:53
User entered 'None (0)'	System	04 Sep 2020 05:46:53

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:46:16', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0fcbcbc2-49a3-4e29-b7f9-812ca925811d'	System	04 Sep 2020 05:46:53
User entered 'None (0)'	System	04 Sep 2020 05:46:53



**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:46:21', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0fcbcbc2-49a3-4e29-b7f9-812ca925811d'	System	04 Sep 2020 05:46:53
User entered 'None (0)'	System	04 Sep 2020 05:46:53

US3292023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:46:37', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0fcbbcb2-49a3-4e29-b7f9-812ca925811d'	System	04 Sep 2020 05:46:53
User entered 'No (N)'	System	04 Sep 2020 05:46:53

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T00:46:51', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '0fcbcbc2-49a3-4e29-b7f9-812ca925811d' User entered '04 Sep 2020 00:46'	System	04 Sep 2020 05:46:53
	System	04 Sep 2020 05:46:53

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 4'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:14:35', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'd52dfdec-2fc4-4655-b2e1-aa0cfead1a79'	System	05 Sep 2020 04:16:30
User entered 'None (0)'	System	05 Sep 2020 04:16:30

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:14:47', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'd52dfdec-2fc4-4655-b2e1-aa0cfead1a79'	System	05 Sep 2020 04:16:30
User entered 'None (0)'	System	05 Sep 2020 04:16:30



**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:14:58', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'd52dfdec-2fc4-4655-b2e1-aa0cfead1a79'	System	05 Sep 2020 04:16:30
User entered 'None (0)'	System	05 Sep 2020 04:16:30

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:15:07', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'd52dfdec-2fc4-4655-b2e1-aa0cfead1a79'	System	05 Sep 2020 04:16:30
User entered 'None (0)'	System	05 Sep 2020 04:16:30

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:15:13', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'd52dfdec-2fc4-4655-b2e1-aa0cfead1a79'	System	05 Sep 2020 04:16:30
User entered 'None (0)'	System	05 Sep 2020 04:16:30

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:15:18', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'd52dfdec-2fc4-4655-b2e1-aa0cfead1a79'	System	05 Sep 2020 04:16:30
User entered 'None (0)'	System	05 Sep 2020 04:16:30

US3292023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:15:42', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'd52dfdec-2fc4-4655-b2e1-aa0cfead1a79'	System	05 Sep 2020 04:16:30
User entered 'No (N)'	System	05 Sep 2020 04:16:30

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-04T23:16:28', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'd52dfdec-2fc4-4655-b2e1-aa0cfead1a79'	System	05 Sep 2020 04:16:30
User entered '04 Sep 2020 23:16'	System	05 Sep 2020 04:16:30

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 17:50:59



**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 5'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:51:30', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7c399cf8-abfc-4026-b5d2-960f1f4b22aa'	System	06 Sep 2020 04:53:01
User entered 'None (0)'	System	06 Sep 2020 04:53:01

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:51:34', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7c399cf8-abfc-4026-b5d2-960f1f4b22aa'	System	06 Sep 2020 04:53:01
User entered 'None (0)'	System	06 Sep 2020 04:53:01

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:51:40', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7c399cf8-abfc-4026-b5d2-960f1f4b22aa'	System	06 Sep 2020 04:53:01
User entered 'None (0)'	System	06 Sep 2020 04:53:01

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:51:48', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7c399cf8-abfc-4026-b5d2-960f1f4b22aa'	System	06 Sep 2020 04:53:01
User entered 'None (0)'	System	06 Sep 2020 04:53:01

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:52:09', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7c399cf8-abfc-4026-b5d2-960f1f4b22aa'	System	06 Sep 2020 04:53:01
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	06 Sep 2020 04:53:01

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:52:14', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7c399cf8-abfc-4026-b5d2-960f1f4b22aa'	System	06 Sep 2020 04:53:01
User entered 'None (0)'	System	06 Sep 2020 04:53:01

US3292023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:52:19', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7c399cf8-abfc-4026-b5d2-960f1f4b22aa'	System	06 Sep 2020 04:53:01
User entered 'No (N)'	System	06 Sep 2020 04:53:01



**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-05T23:52:57', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '7c399cf8-abfc-4026-b5d2-960f1f4b22aa'	System	06 Sep 2020 04:53:01
User entered '05 Sep 2020 23:52'	System	06 Sep 2020 04:53:01

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 6'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:56:45', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'a3c20e73-7702-4e82-b80f-2ce99916b94b'	System	07 Sep 2020 02:58:03
User entered 'None (0)'	System	07 Sep 2020 02:58:03

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:56:49', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'a3c20e73-7702-4e82-b80f-2ce99916b94b'	System	07 Sep 2020 02:58:03
User entered 'None (0)'	System	07 Sep 2020 02:58:03

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:56:57', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'a3c20e73-7702-4e82-b80f-2ce99916b94b'	System	07 Sep 2020 02:58:03
User entered 'None (0)'	System	07 Sep 2020 02:58:03

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:57:06', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'a3c20e73-7702-4e82-b80f-2ce99916b94b'	System	07 Sep 2020 02:58:03
User entered 'None (0)'	System	07 Sep 2020 02:58:03



**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:57:11', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'a3c20e73-7702-4e82-b80f-2ce99916b94b'	System	07 Sep 2020 02:58:03
User entered 'None (0)'	System	07 Sep 2020 02:58:03

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:57:15', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'a3c20e73-7702-4e82-b80f-2ce99916b94b'	System	07 Sep 2020 02:58:03
User entered 'None (0)'	System	07 Sep 2020 02:58:03

US3292023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:57:37', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'a3c20e73-7702-4e82-b80f-2ce99916b94b'	System	07 Sep 2020 02:58:03
User entered 'No (N)'	System	07 Sep 2020 02:58:03

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-06T21:57:59', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'a3c20e73-7702-4e82-b80f-2ce99916b94b'	System	07 Sep 2020 02:58:03
User entered '06 Sep 2020 21:57'	System	07 Sep 2020 02:58:03

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 17:50:59
User entered 'Day 7'	System	01 Sep 2020 17:50:59

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:08**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:10:14', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b4af04d8-8847-40c1-a2e0-109079efbb11'	System	08 Sep 2020 03:11:08
User entered 'None (0)'	System	08 Sep 2020 03:11:08



**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:08**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:10:21', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b4af04d8-8847-40c1-a2e0-109079efbb11'	System	08 Sep 2020 03:11:08
User entered 'None (0)'	System	08 Sep 2020 03:11:08

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:08**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:10:25', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b4af04d8-8847-40c1-a2e0-109079efbb11'	System	08 Sep 2020 03:11:08
User entered 'None (0)'	System	08 Sep 2020 03:11:08

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:08**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:10:30', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b4af04d8-8847-40c1-a2e0-109079efbb11'	System	08 Sep 2020 03:11:08
User entered 'None (0)'	System	08 Sep 2020 03:11:08

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:08**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:10:34', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b4af04d8-8847-40c1-a2e0-109079efbb11'	System	08 Sep 2020 03:11:08
User entered 'None (0)'	System	08 Sep 2020 03:11:08

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:08**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:10:40', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b4af04d8-8847-40c1-a2e0-109079efbb11'	System	08 Sep 2020 03:11:08
User entered 'None (0)'	System	08 Sep 2020 03:11:08

US3292023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:10:44', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b4af04d8-8847-40c1-a2e0-109079efbb11'	System	08 Sep 2020 03:11:08
User entered 'No (N)'	System	08 Sep 2020 03:11:08

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-09-07T22:11:02', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'b4af04d8-8847-40c1-a2e0-109079efbb11'	System	08 Sep 2020 03:11:08
User entered '07 Sep 2020 22:11'	System	08 Sep 2020 03:11:08

**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 17:50:59



**US3292023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:55:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 17:50:59

US3292023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	11 Sep 2020 14:23:11

**US3292023**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:08**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Kristy Trevino (b) (4) (b) (4)	11 Sep 2020 14:23:11

US3292023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:08

[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)	11 Sep 2020 14:23:11

**US3292023**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Kristy Trevino (b) (4) (b) (4)	11 Sep 2020 14:23:11

US3292023

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	11 Sep 2020 14:23:18

**US3292023**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Sep 2020 14:23:18

US3292023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	17 Sep 2020 15:05:25



**US3292023**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:08**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Kristy Trevino (b) (4) (b) (4)	17 Sep 2020 15:05:25

US3292023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:08

[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)	17 Sep 2020 15:05:25

**US3292023**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Kristy Trevino (b) (4) (b) (4)	17 Sep 2020 15:05:25

US3292023

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	17 Sep 2020 15:05:33

**US3292023**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Sep 2020 15:05:33

US3292023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	24 Sep 2020 14:04:43

US3292023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Sep 2020'	Kristy Trevino (b) (4) (b) (4)	24 Sep 2020 14:04:43

US3292023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:08

[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 Sep 2020 14:04:43



**US3292023**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Kristy Trevino (b) (4) (b) (4)	24 Sep 2020 14:04:43

US3292023

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	24 Sep 2020 14:04:47

**US3292023**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Sep 2020 14:04:47

US3292023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kevin Martinez (b) (4) (b) (4)	29 Sep 2020 20:39:28

US3292023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:08

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Kevin Martinez (b) (4) (b) (4)	29 Sep 2020 20:39:28

US3292023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:55:08

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Kevin Martinez (b) (4) (b) (4)	29 Sep 2020 20:39:28

**US3292023**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:55:08**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	29 Sep 2020 20:39:28

US3292023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:08

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kevin Martinez (b) (4) (b) (4)	29 Sep 2020 20:40:34



US3292023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Kevin Martinez (b) (4) (b) (4)	29 Sep 2020 20:40:34

US3292023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:08

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User entered '13:59'	Kevin Martinez (b) (4) (b) (4)	29 Sep 2020 20:40:34

**US3292023**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:08**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 13:59'	System	29 Sep 2020 20:40:34

US3292023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:08

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.5' C	Kevin Martinez (b) (4) (b) (4)	29 Sep 2020 20:40:34

US3292023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:08

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Kevin Martinez (b) (4) (b) (4)	29 Sep 2020 20:40:34

US3292023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:08

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kevin Martinez (b) (4) (b) (4)	29 Sep 2020 20:40:34

US3292023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '80'	Kevin Martinez (b) (4) (b) (4)	29 Sep 2020 20:40:34

**US3292023**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:08**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Sep 2020 20:40:34



US3292023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	Kevin Martinez (b) (4) (b) (4)	29 Sep 2020 20:40:34

**US3292023**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:08**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Sep 2020 20:40:34

US3292023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '111'	Kevin Martinez (b) (4) (b) (4)	29 Sep 2020 20:40:34

**US3292023**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:55:08**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Sep 2020 20:40:34

US3292023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '72'	Kevin Martinez (b) (4) (b) (4)	29 Sep 2020 20:40:34

US3292023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:55:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Sep 2020 20:40:34

US3292023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:08

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Kevin Martinez (b) (4) (b) (4)	29 Sep 2020 20:40:39

US3292023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:55:08

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Kevin Martinez (b) (4) (b) (4)	29 Sep 2020 20:40:39



US3292023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:08

Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kevin Martinez (b) (4) (b) (4)	29 Sep 2020 20:40:55

US3292023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Kevin Martinez (b) (4) (b) (4)	29 Sep 2020 20:40:55

US3292023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:55:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '14:29'	Kevin Martinez (b) (4) (b) (4)	29 Sep 2020 20:40:55

**US3292023**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:55:08**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 14:29'	System	29 Sep 2020 20:40:55

US3292023

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kevin Martinez (b) (4) (b) (4)	29 Sep 2020 20:41:00

**US3292023**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Sep 2020 20:41:00

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 64'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-10-06T14:41:39', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'f1a7c21a-337f-4d8d-a9e2-40cb96980080'	System	06 Oct 2020 19:42:48
User entered 'No (N)'	System	06 Oct 2020 19:42:48



**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

Have you been exposed to someone with 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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-10-06T14:42:00', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'f1a7c21a-337f-4d8d-a9e2-40cb96980080'	System	06 Oct 2020 19:42:48
User entered 'No (N)'	System	06 Oct 2020 19:42:48

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-10-06T14:42:44', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: 'f1a7c21a-337f-4d8d-a9e2-40cb96980080' User entered '06 Oct 2020 14:42:44'	System	06 Oct 2020 19:42:48
	System	06 Oct 2020 19:42:48

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered '04 Oct 2020 00:01'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered '08 Oct 2020 23:59'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 71'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-10-14T11:30:00', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '09f06ca3-ce95-4da3-9ef2-ef5b1ce32187'	System	14 Oct 2020 16:30:42
User entered 'No (N)'	System	14 Oct 2020 16:30:42

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

Have you been exposed to someone with 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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-10-14T11:30:16', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '09f06ca3-ce95-4da3-9ef2-ef5b1ce32187'	System	14 Oct 2020 16:30:42
User entered 'No (N)'	System	14 Oct 2020 16:30:42

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-10-14T11:30:39', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '09f06ca3-ce95-4da3-9ef2-ef5b1ce32187' User entered '14 Oct 2020 11:30:39'	System	14 Oct 2020 16:30:42
	System	14 Oct 2020 16:30:42



**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered '11 Oct 2020 00:01'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered '15 Oct 2020 23:59'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 78'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-10-20T13:58:43', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '25f6bc3d-7efa-48c7-99f4-32e734d8ab6d' User entered 'No (N)'	System	20 Oct 2020 19:30:57
	System	20 Oct 2020 19:30:57

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

Have you been exposed to someone with 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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-10-20T14:00:52', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '25f6bc3d-7efa-48c7-99f4-32e734d8ab6d'	System	20 Oct 2020 19:30:57
User entered 'No (N)'	System	20 Oct 2020 19:30:57

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-10-20T14:30:50', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '25f6bc3d-7efa-48c7-99f4-32e734d8ab6d' User entered '20 Oct 2020 14:30:50'	System	20 Oct 2020 19:30:57
	System	20 Oct 2020 19:30:57

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered '18 Oct 2020 00:01'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered '22 Oct 2020 23:59'	System	04 Aug 2020 21:09:49



**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 92'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-11-04T16:04:37', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '2daed050-a4f6-4dd4-b5d6-fa51021d8858'	System	04 Nov 2020 22:05:07
User entered 'No (N)'	System	04 Nov 2020 22:05:07

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

Have you been exposed to someone with 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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-11-04T16:04:46', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '2daed050-a4f6-4dd4-b5d6-fa51021d8858'	System	04 Nov 2020 22:05:07
User entered 'No (N)'	System	04 Nov 2020 22:05:07

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-11-04T16:05:04', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '2daed050-a4f6-4dd4-b5d6-fa51021d8858' User entered '04 Nov 2020 16:05:04'	System	04 Nov 2020 22:05:07
	System	04 Nov 2020 22:05:07

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered '01 Nov 2020 00:01'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered '05 Nov 2020 23:59'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 99'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-11-11T05:18:03', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '5bcf6e77-4505-4e32-8336-ef236af3e29b'	System	11 Nov 2020 11:18:41
User entered 'No (N)'	System	11 Nov 2020 11:18:41



**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

Have you been exposed to someone with 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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-11-11T05:18:15', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '5bcf6e77-4505-4e32-8336-ef236af3e29b' User entered 'No (N)'	System	11 Nov 2020 11:18:41
	System	11 Nov 2020 11:18:41

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-11-11T05:18:39', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '5bcf6e77-4505-4e32-8336-ef236af3e29b' User entered '11 Nov 2020 05:18:39'	System	11 Nov 2020 11:18:41
	System	11 Nov 2020 11:18:41

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered '08 Nov 2020 00:01'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered '12 Nov 2020 23:59'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 106'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-11-17T17:49:22', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '575a067a-d165-492e-ba08-d420abb69968' User entered 'No (N)'	System	17 Nov 2020 23:50:18
	System	17 Nov 2020 23:50:18

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

Have you been exposed to someone with 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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-11-17T17:49:55', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '575a067a-d165-492e-ba08-d420abb69968' User entered 'No (N)'	System	17 Nov 2020 23:50:18

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-11-17T17:50:15', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '575a067a-d165-492e-ba08-d420abb69968' User entered '17 Nov 2020 17:50:15'	System	17 Nov 2020 23:50:18
	System	17 Nov 2020 23:50:18



**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered '15 Nov 2020 00:01'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Aug 2020 21:09:49
User entered '19 Nov 2020 23:59'	System	04 Aug 2020 21:09:49

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

**TIMEPOINT**

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Nolan Payton (b) (4)	24 Nov 2020 15:32:35
Amendment Manager: DataPoint Inactivated.	(b) (4)	19 Nov 2020 12:52:45
Data entry locked.	System	04 Aug 2020 21:09:49
User entered 'Day 113'	System	04 Aug 2020 21:09:49

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-11-24T10:47:06', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '94d45ed6-ccda-49cc-a8af-e71ef2dd2fda'	System	24 Nov 2020 16:47:43
User entered 'No (N)'	System	24 Nov 2020 16:47:43
DataPoint activated with code reason code Data required.	Nolan Payton (b) (4)	24 Nov 2020 15:32:35
Amendment Manager: DataPoint Inactivated.	(b) (4)	
	System	19 Nov 2020 12:52:45

US3292023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:55:08

Have you been exposed to someone with 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 (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-11-24T10:47:17', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '94d45ed6-ccda-49cc-a8af-e71ef2dd2fda'	System	24 Nov 2020 16:47:43
User entered 'No (N)'	System	24 Nov 2020 16:47:43
DataPoint activated with code reason code Data required.	Nolan Payton (b) (4)	24 Nov 2020 15:32:35
	(b) (4)	
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611504B2-B98C-42B4-B807-2688DDF48D96)', Time: '2020-11-24T10:47:39', User OID: 'PatientReportedOutcome (US3292023)', ODM File OID: '94d45ed6-ccda-49cc-a8af-e71ef2dd2fda'	System	24 Nov 2020 16:47:43
User entered '24 Nov 2020 10:47:39'	System	24 Nov 2020 16:47:43
DataPoint activated with code reason code Data required.	Nolan Payton (b) (4)	24 Nov 2020 15:32:35
	(b) (4)	
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Nolan Payton (b) (4)	24 Nov 2020 15:32:35
Amendment Manager: DataPoint Inactivated.	(b) (4)	19 Nov 2020 12:52:45
Data entry locked.	System	04 Aug 2020 21:09:49
User entered '22 Nov 2020 00:01'	System	04 Aug 2020 21:09:49

**US3292023**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Nolan Payton (b) (4)	24 Nov 2020 15:32:35
Amendment Manager: DataPoint Inactivated.	(b) (4)	19 Nov 2020 12:52:45
Data entry locked.	System	04 Aug 2020 21:09:49
User entered '26 Nov 2020 23:59'	System	04 Aug 2020 21:09:49



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '01 Oct 2020 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '05 Oct 2020 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '08 Oct 2020 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '12 Oct 2020 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '15 Oct 2020 00:01'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '19 Oct 2020 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '22 Oct 2020 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '26 Oct 2020 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '29 Oct 2020 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '02 Nov 2020 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '05 Nov 2020 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '09 Nov 2020 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '12 Nov 2020 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '16 Nov 2020 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 12:52:45



**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 12:52:45

**US3292023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:55:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:52:45
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 12:52:45

US3292023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nathan Cortez (b) (4) [REDACTED]	27 Oct 2020 19:47:54

US3292023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Oct 2020'	Nathan Cortez (b) (4) [REDACTED]	27 Oct 2020 19:47:54



US3292023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:55:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Nathan Cortez (b) (4)	27 Oct 2020 19:47:54

**US3292023**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:55:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Nathan Cortez (b) (4)	27 Oct 2020 19:47:54

US3292023

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:55:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nathan Cortez (b) (4) [REDACTED]	27 Oct 2020 19:48:00

**US3292023**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:55:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Oct 2020 19:48:00

**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 26 Nov 2020 10:55:08**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:08:33
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:36:24

**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:31
User entered 'USA-US072-2020-mRNA-1273-P301000007'	System	28 Oct 2020 17:21:27
User entered 'New'	(b) (4), (b) (6)	28 Oct 2020 17:21:27

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:08

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Diabetic complications, HLT: Diabetic complications NEC, PT: Diabetic ketoacidosis, LLT: Diabetic ketoacidosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 18:59:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 18:59:27
Data point term sent to Coder	System	27 Oct 2020 18:58:58
User entered 'Diabetic ketoacidosis'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39



**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered 'No (N)'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered 'No (N)'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered '22 Oct 2020'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered empty.	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 18:58:39

**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered 'No (N)'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered '26 Oct 2020'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered empty.	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39



**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 18:58:39

**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered 'Grade 3/Severe (Grade 3/Severe)'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered '0'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered '0'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered '1'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered '22 Oct 2020'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:08

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered '26 Oct 2020'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39



**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered 'No (N)'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered empty.	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered '0'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered '0'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered '0'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered 'Not Applicable (NOT APPLICABLE)'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39



**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered '0'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered '1'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered '0'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50
User entered empty.	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:08

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 19:32:34
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 19:32:09
User closed query 'PV Query: Please provide any available details on the subject's malfunctioning insulin pump. Was a co-suspect medication implicated in the reported event?' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 16:27:45
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 16:27:43
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 16:27:42
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 16:27:39
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Will be provided once medical records become available' (Site from Safety).	Darlington Akahara (b) (4)	08 Nov 2020 22:26:14

US3292023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:55:08

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Will be provided once medical records become available' (Site from Safety).	Darlington Akahara (b) (4)	08 Nov 2020 22:25:57
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'COVID-19 testing not done, as per patient. Will note in progress note.' (Site from Safety).	Antonio Gutierrez (b) (4)	06 Nov 2020 19:42:02
Query 'PV Query: Please provide any available details on the subject's malfunctioning insulin pump. Was a co-suspect medication implicated in the reported event?' answered with 'As of conversation with patient on 06NOV2020, pt states that scar tissue in patient's skin was preventing the flow of insulin. This conversation will be noted in progress note.' (Site from Safety).	Antonio Gutierrez (b) (4)	06 Nov 2020 19:41:32
User opened query 'PV Query: Please provide any available details on the subject's malfunctioning insulin pump. Was a co-suspect medication implicated in the reported event?' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 23:12:43
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 23:12:23
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 23:12:02
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 23:11:48
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:50

**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Patient contacted staff today, 27OCT2020, to state that he had been hospitalized recently due to Diabetic Ketoacidosis. On Thursday, 22OCT2020, patient states that he was not feeling well due to an insulin pump that was not functioning correctly. He states that he had been waiting for a replacement that was overdue for delivery. Patient states that he had checked his blood sugar, which had been registering between 500 and 700. The lowest reading registered at 468. After realizing that his levels would not drop to normal levels, he contacted EMS and was transported to a local hospital. Upon being evaluated by ER physicians, the patient was started on an insulin drip. The patient was not able to remember any other medications that he may have been given. Patient was discharged in stable condition on 26OCT2020. Medical records will be requested as soon as possible. No further information available at this time.'	Antonio Gutierrez (b) (4)	27 Oct 2020 18:58:39



**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Oct 2020 18:58:39

**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Oct 2020 18:58:39

**US3292023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	27 Oct 2020 18:58:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:55:08

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User closed query 'Per ETRTR: Please add ConMeds provided for SAE "Diabetic Ketoacidosis ", thanks.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 18:05:45
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:09:26
Query 'Per ETRTR: Please add ConMeds provided for SAE "Diabetic Ketoacidosis ", thanks.' answered with 'ConMeds updated ' (Site from CRA).	Antonio Gutierrez (b) (4)	04 Nov 2020 00:08:00
User opened query 'Per ETRTR: Please add ConMeds provided for SAE "Diabetic Ketoacidosis ", thanks.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 19:02:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 11:54:30

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 11:59:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 11:59:20
Data point term sent to Coder	System	07 Aug 2020 11:58:34
User entered 'Vitamin B12'	(b) (4), (b) (6)	07 Aug 2020 11:57:40

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 16:56:33
Query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 15:26:56
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 15:26:49
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 15:26:49
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 14:30:54
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 11:57:40

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Preventative'	(b) (4), (b) (6)	07 Aug 2020 11:57:40

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '50'	(b) (4), (b) (6)	07 Aug 2020 11:57:40



**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Other (OTHER)'	(b) (4), (b) (6)	07 Aug 2020 11:57:40

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:08

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'mcg'	(b) (4), (b) (6)	07 Aug 2020 11:57:40

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Aug 2020 11:57:40

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 11:57:40

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Aug 2020 11:57:40

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:08**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 11:57:40

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
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)	11 Aug 2020 13:42:01
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	07 Aug 2020 12:01:09
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	07 Aug 2020 11:57:40
User entered 'un UNK 2016'	(b) (4), (b) (6)	07 Aug 2020 11:57:40

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 11:57:40



**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 11:57:40

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 11:57:40

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:55:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 11:57:40

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 11:57:40

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 11:57:40

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 11:57:40

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 12:01:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 12:01:05
Data point term sent to Coder	System	07 Aug 2020 12:00:34
User entered 'Vitamin C'	(b) (4), (b) (6)	07 Aug 2020 11:59:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Query 'Per CDM: Response noted however, indication is supplement. Please consider updating to Yes or provide explanation.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	17 Nov 2020 21:52:18
DataPoint Un-verified.	Dawn Killian (b) (4)	17 Nov 2020 21:52:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Dawn Killian (b) (4)	17 Nov 2020 21:52:04
User opened query 'Per CDM: Response noted however, indication is supplement. Please consider updating to Yes or provide explanation.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 20:30:04
User closed query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 20:30:04
Query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' answered with 'indication is supplement.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 15:27:26
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 14:31:05
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 11:59:37



**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:55:08**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Supplement'	(b) (4), (b) (6)	07 Aug 2020 11:59:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '1500'	(b) (4), (b) (6)	07 Aug 2020 11:59:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Aug 2020 11:59:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:08

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 11:59:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Aug 2020 11:59:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 11:59:37

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:55:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Aug 2020 11:59:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 11:59:37



US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
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)	11 Aug 2020 13:42:05
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	07 Aug 2020 12:01:26
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	07 Aug 2020 11:59:37
User entered 'un UNK 2016'	(b) (4), (b) (6)	07 Aug 2020 11:59:37

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 11:59:37

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:55:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 11:59:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 11:59:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:55:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 11:59:37

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:55:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 11:59:37

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 11:59:37

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 11:59:37



US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 12:04:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 12:04:13
Data point term sent to Coder	System	07 Aug 2020 12:03:38
User entered 'Duloxetine'	(b) (4), (b) (6)	07 Aug 2020 12:03:33

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:36:57
Query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:05:19
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	21 Sep 2020 20:05:10
User opened query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:31:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:03:33

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:55:08**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Depression'	(b) (4), (b) (6)	07 Aug 2020 12:03:33

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:55:08**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '60'	(b) (4), (b) (6)	07 Aug 2020 12:03:33

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Aug 2020 12:03:33

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:55:08**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:03:33

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:55:08**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'twice daily (BID)'	(b) (4), (b) (6)	07 Aug 2020 12:03:33

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:03:33



**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:55:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Aug 2020 12:03:33

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:55:08**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:03:33

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
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)	11 Aug 2020 13:42:12
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)	07 Aug 2020 12:03:48
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	07 Aug 2020 12:03:33
User entered 'un UNK 2017'	(b) (4), (b) (6)	07 Aug 2020 12:03:33

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 12:03:33

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:55:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:03:33

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:55:08**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:03:33

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:55:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 12:03:33

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:55:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	07 Aug 2020 12:03:33



**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 12:03:33

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 12:03:33

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 22:20:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 22:20:13
Data point term sent to Coder	System	07 Aug 2020 12:05:38
User entered 'Gabapentin'	(b) (4), (b) (6)	07 Aug 2020 12:05:21

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM). Query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:37:06
User entered 'No (N)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:06:45
User opened query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:32:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:05:21

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Please update the indication to reflect the specific type of NEUROPATHY (Sensory or Motor). Please reconcile with the Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:37:28
Query 'Per DM CLR: Please update the indication to reflect the specific type of NEUROPATHY (Sensory or Motor). Please reconcile with the Med History eCRFs as appropriate.' answered with 'CORRECT AS IS PER PATIENT' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:06:58
User opened query 'Per DM CLR: Please update the indication to reflect the specific type of NEUROPATHY (Sensory or Motor). Please reconcile with the Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:32:19
User entered 'Diabetic peripheral neuropathy'	(b) (4), (b) (6)	07 Aug 2020 12:05:21

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '300'	(b) (4), (b) (6)	07 Aug 2020 12:05:21

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:08**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Aug 2020 12:05:21

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:08

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:05:21



**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:08**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'three times daily (TID)'	(b) (4), (b) (6)	07 Aug 2020 12:05:21

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:05:21

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Aug 2020 12:05:21

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:05:21

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
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)	11 Aug 2020 13:42:20
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)	07 Aug 2020 12:05:42
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	07 Aug 2020 12:05:21
User entered 'un UNK 2013'	(b) (4), (b) (6)	07 Aug 2020 12:05:21

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 12:05:21

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:05:21

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:55:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:05:21



**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:08**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 12:05:21

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	07 Aug 2020 12:05:21

US3292023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 12:05:21

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 12:05:21

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 07:54:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 07:54:15
Data point term sent to Coder	System	07 Aug 2020 12:14:41
User entered 'Humalog'	(b) (4), (b) (6)	07 Aug 2020 12:14:08

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM). Query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:37:49
User entered 'No (N)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:07:21
User opened query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:35:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:14:08

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:08**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Type 1 Diabetes'	(b) (4), (b) (6)	07 Aug 2020 12:14:08

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:08

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please remove and record the dose unit 'U' in the dose unit section. Please update dose and dose unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 16:11:00
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
Query 'Per DM CLR: Please remove and record the dose unit 'U' in the dose unit section. Please update dose and dose unit as appropriate.' answered with 'updated; per subject 100 IU is correct dose' (Site from DM).	Dawn Killian (b) (4)	28 Oct 2020 19:44:12
User entered '100' reason for change: Data Entry Error	Dawn Killian (b) (4)	28 Oct 2020 19:43:41
User opened query 'Per DM CLR: Please remove and record the dose unit 'U' in the dose unit section. Please update dose and dose unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 02:24:19
User closed query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication (i.e., High dose). Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:38:04
Query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication (i.e., High dose). Please correct the dosage or provide explanation for alternate dosage.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:11:41
User entered 'U-100' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:11:33
User opened query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication (i.e., High dose). Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:34:35
User entered '100'	(b) (4), (b) (6)	07 Aug 2020 12:14:08



US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'IU (IU)' reason for change: Data Entry Error	Dawn Killian (b) (4)	28 Oct 2020 19:43:41
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4)	
User entered 'Other (OTHER)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:11:33
User entered 'IU (IU)'	(b) (4)	
	(b) (4), (b) (6)	07 Aug 2020 12:14:08

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:08

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty; reason for change Data Entry Error	Dawn Killian (b) (4)	28 Oct 2020 19:43:41
User entered 'UNITS' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:11:33
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:14:08

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:08**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'other (OTHER)'	(b) (4), (b) (6)	07 Aug 2020 12:14:08

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:08**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'AC'	(b) (4), (b) (6)	07 Aug 2020 12:14:08

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	07 Aug 2020 12:14:08

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:08**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:14:08

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of DIABETES. Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 16:11:03
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of DIABETES. Please review and reconcile Con Med and Med History start dates as appropriate.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:24:20
User entered empty; reason for change Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:11:33
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of DIABETES. Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:35:25
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)	11 Aug 2020 13:42:29
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.' answered with 'Medication is ongoing, correct as entered.' (Site from System).	(b) (4), (b) (6)	07 Aug 2020 12:52:20
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	07 Aug 2020 12:14:08
User entered 'un UNK 1995'	(b) (4), (b) (6)	07 Aug 2020 12:14:08

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:55:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '1' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:11:33
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 12:14:08



**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:14:08

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:08**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:14:08

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:08**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 12:14:08

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 12:14:08

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 12:14:08

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 12:14:08

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 12:16:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 12:16:13
Data point term sent to Coder	System	07 Aug 2020 12:15:42
User entered 'Levothyroxine'	(b) (4), (b) (6)	07 Aug 2020 12:15:20

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM). Query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:38:28
User entered 'No (N)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:12:28
User opened query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:38:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:15:20



**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:08**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Hypothyroid'	(b) (4), (b) (6)	07 Aug 2020 12:15:20

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '175'	(b) (4), (b) (6)	07 Aug 2020 12:15:20

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:08

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR-Request: Response noted. However, Levothyroxine is recorded as UG/Micrograms/MCG. Please review if UG is more appropriate to be recorded. Please update the unit as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:32:20
	(b) (4), (b) (6)	04 Nov 2020 21:10:48
Query 'Per DM CLR-Request: Response noted. However, Levothyroxine is recorded as UG/Micrograms/MCG. Please review if UG is more appropriate to be recorded. Please update the unit as appropriate.' answered with 'updated' (Site from DM). User entered 'ug (ug)' reason for change: Data Entry Error	Dawn Killian (b) (4) (b) (4)	28 Oct 2020 19:46:05
User opened query 'Per DM CLR-Request: Response noted. However, Levothyroxine is recorded as UG/Micrograms/MCG. Please review if UG is more appropriate to be recorded. Please update the unit as appropriate.' (Site from DM).	Dawn Killian (b) (4) (b) (4)	28 Oct 2020 19:45:49
User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 06:23:57
Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate.' answered with 'CORRECT PER PATIENT' (Site from DM).	Victoria Hernandez (b) (4) (b) (4)	21 Sep 2020 20:12:54
User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:38:23
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Aug 2020 12:15:20

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:08

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:15:20

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:08**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Aug 2020 12:15:20

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:15:20

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Aug 2020 12:15:20

US3292023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:08**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:15:20



US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
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)	11 Aug 2020 13:42:38
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)	07 Aug 2020 12:52:05
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	07 Aug 2020 12:15:20
User entered 'un UNK 2010'	(b) (4), (b) (6)	07 Aug 2020 12:15:20

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 12:15:20

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:15:20

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:08**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:15:20

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:55:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 12:15:20

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 12:15:20

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 12:15:20

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 12:15:20



US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:08

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 14:52:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 14:52:21
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
Data point term sent to Coder	System	28 Oct 2020 19:48:19
Coding entries removed.	Dawn Killian (b) (4) (b) (4)	28 Oct 2020 19:47:59
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 10:11:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 10:11:50
Data point term sent to Coder	System	21 Sep 2020 20:25:33
Coding entries removed.	Victoria Hernandez (b) (4) (b) (4)	21 Sep 2020 20:25:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 12:47:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 12:47:20
Data point term sent to Coder	System	07 Aug 2020 12:16:42
User entered 'Lisinopril'	(b) (4), (b) (6)	07 Aug 2020 12:16:23

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Dawn Killian (b) (4)	28 Oct 2020 19:47:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Victoria Hernandez (b) (4)	21 Sep 2020 20:25:01
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:16:23

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:08

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note this medication is not given as a prophylaxis. It is used to treat a condition. Review and either remove the prophylaxis indication and add a condition to the Med History eCRF to match this medication or clarify the recorded indication. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 16:12:20
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 16:12:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'this drug can be used for prevention; correct as is' (Site from DM).	Dawn Killian (b) (4) (b) (4)	28 Oct 2020 19:48:12
User entered 'KIDNEY DISEASE prevention' reason for change: Data Entry Error	Dawn Killian (b) (4) (b) (4)	28 Oct 2020 19:47:59
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 09:05:55
Query 'Per DM CLR: Please note this medication is not given as a prophylaxis. It is used to treat a condition. Review and either remove the prophylaxis indication and add a condition to the Med History eCRF to match this medication or clarify the recorded indication. ' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4) (b) (4)	21 Sep 2020 20:25:06
User entered 'KIDNEY DISEASE' reason for change: Data Entry Error	Victoria Hernandez (b) (4) (b) (4)	21 Sep 2020 20:25:01

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:08

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note this medication is not given as a prophylaxis. It is used to treat a condition. Review and either remove the prophylaxis indication and add a condition to the Med History eCRF to match this medication or clarify the recorded indication. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:38:58
User entered 'Kidney prevention'	(b) (4), (b) (6)	07 Aug 2020 12:16:23

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:08**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '20'	(b) (4), (b) (6)	07 Aug 2020 12:16:23

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Aug 2020 12:16:23

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:08**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:16:23

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:08**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Aug 2020 12:16:23



**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:08**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:16:23

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Aug 2020 12:16:23

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:08**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:16:23

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:55:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
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)	11 Aug 2020 13:42:43
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)	07 Aug 2020 12:51:51
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	07 Aug 2020 12:16:23
User entered 'un UNK 2000'	(b) (4), (b) (6)	07 Aug 2020 12:16:23

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 12:16:23

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:16:23

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:08**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:16:23

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:08**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 12:16:23



**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 12:16:23

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 12:16:23

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 12:16:23

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:08

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: BETA BLOCKING AGENTS, PRODUCT: BRIMONIDINE TARTRATE;TIMOLOL MALEATE, PRODUCTSYNONYM: COMBIGAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 20:37:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 20:37:42
Data point term sent to Coder	System	21 Sep 2020 20:37:03
Data point term sent to Coder	System	21 Sep 2020 20:36:02
Coding entries removed.	Victoria Hernandez (b) (4) (b) (4)	21 Sep 2020 20:35:30
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: BETA BLOCKING AGENTS, PRODUCT: BRIMONIDINE TARTRATE;TIMOLOL MALEATE, PRODUCTSYNONYM: COMBIGAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 12:23:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 12:23:12
Data point term sent to Coder	System	07 Aug 2020 12:21:47
User entered 'Combigan'	(b) (4), (b) (6)	07 Aug 2020 12:21:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:09:09
Query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:35:42
User opened query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:29:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:21:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:08

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and update to reflect if this involves the LEFT, RIGHT or BILATERAL EYES. Update and reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 16:09:12
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
Query 'Per DM CLR: Please review and update to reflect if this involves the LEFT, RIGHT or BILATERAL EYES. Update and reconcile with the AE and Med History eCRFs as appropriate.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:36:08
User entered 'BILATERAL GLAUCOMA' reason for change: Data Entry Error	(b) (4)	21 Sep 2020 20:35:30
User opened query 'Per DM CLR: Please review and update to reflect if this involves the LEFT, RIGHT or BILATERAL EYES. Update and reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:29:27
User entered 'Glaucoma'	(b) (4), (b) (6)	07 Aug 2020 12:21:34

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:55:08**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '3'	(b) (4), (b) (6)	07 Aug 2020 12:21:34

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:55:08**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Other (OTHER)'	(b) (4), (b) (6)	07 Aug 2020 12:21:34



**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:55:08**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'drops'	(b) (4), (b) (6)	07 Aug 2020 12:21:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 12:51:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Aug 2020 12:51:18
User entered 'twice daily (BID)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Aug 2020 12:51:18
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 12:21:34
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:21:34

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:55:08**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:21:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:08

[Route of administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Verify if "OPHTHALMIC" is a more appropriate recording. Please update route as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:09:15
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Verify if "OPHTHALMIC" is a more appropriate recording. Please update route as appropriate.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:36:37
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4)	21 Sep 2020 20:36:27
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Verify if "OPHTHALMIC" is a more appropriate recording. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:29:06
User entered 'Intraocular (INTRAOCULAR)'	(b) (4), (b) (6)	07 Aug 2020 12:21:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'OPHTHALMIC' reason for change:	Victoria Hernandez (b) (4)	21 Sep 2020 20:36:27
Data Entry Error	(b) (4)	
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:21:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
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)	11 Aug 2020 13:42:48
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)	07 Aug 2020 12:51:32
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	07 Aug 2020 12:21:34
User entered 'un UNK 2007'	(b) (4), (b) (6)	07 Aug 2020 12:21:34

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 12:21:34

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:55:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:21:34



**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:55:08**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:21:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:55:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 12:21:34

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:55:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	07 Aug 2020 12:51:18
User entered empty.	System	07 Aug 2020 12:21:34

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 12:51:18
User entered empty.	System	07 Aug 2020 12:21:34

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 12:51:18
User entered empty.	System	07 Aug 2020 12:21:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: LATANOPROST;NETARSUDIL MESILATE, PRODUCTSYNONYM: ROCKLATAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 20:38:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 20:38:45
Data point term sent to Coder Coding entries removed.	System Victoria Hernandez (b) (4) (b) (4)	21 Sep 2020 20:38:04 21 Sep 2020 20:37:22
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: LATANOPROST;NETARSUDIL MESILATE, PRODUCTSYNONYM: ROCKLATAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 12:25:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 12:25:20
Data point term sent to Coder User entered 'Rocklatan'	System (b) (4), (b) (6)	07 Aug 2020 12:23:48 07 Aug 2020 12:23:29

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query ' Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM). Query '	(b) (4), (b) (6)	30 Sep 2020 09:41:27
Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:37:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	21 Sep 2020 20:37:22
User opened query ' Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:39:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:23:29

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Please review and update to reflect if this involves the LEFT, RIGHT or BILATERAL EYES. Update and reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:41:34
Query 'Per DM CLR: Please review and update to reflect if this involves the LEFT, RIGHT or BILATERAL EYES. Update and reconcile with the AE and Med History eCRFs as appropriate.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:37:35
User entered 'BILATERAL GLAUCOMA' reason for change: Data Entry Error	(b) (4)	21 Sep 2020 20:37:22
User opened query 'Per DM CLR: Please review and update to reflect if this involves the LEFT, RIGHT or BILATERAL EYES. Update and reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:39:20
User entered 'Glaucoma'	(b) (4), (b) (6)	07 Aug 2020 12:23:29



**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:55:08**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '3'	(b) (4), (b) (6)	07 Aug 2020 12:23:29

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:55:08**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Other (OTHER)'	(b) (4), (b) (6)	07 Aug 2020 12:23:29

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:55:08**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'drops'	(b) (4), (b) (6)	07 Aug 2020 12:23:29

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:55:08**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'twice daily (BID)'	(b) (4), (b) (6)	07 Aug 2020 12:23:29

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:23:29

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:08

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Verify if "OPHTHALMIC" is a more appropriate recording. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:41:39
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Verify if "OPHTHALMIC" is a more appropriate recording. Please update route as appropriate.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:37:39
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4)	21 Sep 2020 20:37:22
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Verify if "OPHTHALMIC" is a more appropriate recording. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:39:30
User entered 'Intraocular (INTRAOCULAR)'	(b) (4), (b) (6)	07 Aug 2020 12:23:29

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'OPHTHALMIC' reason for change:	Victoria Hernandez (b) (4)	21 Sep 2020 20:37:22
Data Entry Error	(b) (4)	
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:23:29

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
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)	11 Aug 2020 13:42:54
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)	07 Aug 2020 12:49:29
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	07 Aug 2020 12:23:29
User entered 'un UNK 2007'	(b) (4), (b) (6)	07 Aug 2020 12:23:29



**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 12:23:29

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:55:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:23:29

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:23:29

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:55:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 12:23:29

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:55:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	07 Aug 2020 12:23:29

US3292023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 12:23:29

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 12:23:29

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:08

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and provide the strength in the medication name as there are varying drug strength for this medication. Review and update eCRF as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:11:35
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 18:11:26
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:35:43
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: LATANOPROST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 21:10:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	22 Sep 2020 01:42:47
Data point term sent to Coder	System	22 Sep 2020 01:42:47
Query 'Per DM CLR: Please review and provide the strength in the medication name as there are varying drug strength for this medication. Review and update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:40:09
User entered 'LATANOPROST 0.005%' reason for change: Data Entry Error	(b) (4)	21 Sep 2020 20:39:49
Data point term sent to Coder	System	(b) (4)
Coding entries removed.	Victoria Hernandez (b) (4)	21 Sep 2020 20:39:08
User opened query 'Per DM CLR: Please review and provide the strength in the medication name as there are varying drug strength for this medication. Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 20:38:52
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: LATANOPROST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 04:36:24
	(b) (4)	07 Aug 2020 12:36:14



US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:08

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	07 Aug 2020 12:36:14
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	07 Aug 2020 12:34:50
User entered 'Latanoprost'	(b) (4), (b) (6)	07 Aug 2020 12:34:32

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM). Query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:44:10
User entered 'No (N)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:39:56
User opened query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4)	21 Sep 2020 20:38:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 04:36:34
	(b) (4), (b) (6)	07 Aug 2020 12:34:32

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query ' Per DM CLR: Please review and update to reflect if this involves the LEFT, RIGHT or BILATERAL EYES. Update and reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM). Query '	(b) (4), (b) (6)	30 Sep 2020 09:44:13
Per DM CLR: Please review and update to reflect if this involves the LEFT, RIGHT or BILATERAL EYES. Update and reconcile with the AE and Med History eCRFs as appropriate.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:40:00
User entered 'BILATERAL GLAUCOMA' reason for change: Data Entry Error	(b) (4)	21 Sep 2020 20:38:52
User opened query ' Per DM CLR: Please review and update to reflect if this involves the LEFT, RIGHT or BILATERAL EYES. Update and reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:36:16
User entered 'Glaucoma'	(b) (4), (b) (6)	07 Aug 2020 12:34:32

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:08**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '2'	(b) (4), (b) (6)	07 Aug 2020 12:34:32

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:08**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Other (OTHER)'	(b) (4), (b) (6)	07 Aug 2020 12:34:32

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:08**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'drops'	(b) (4), (b) (6)	07 Aug 2020 12:34:32

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Aug 2020 12:34:32

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:34:32



US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:08

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Verify if "OPHTHALMIC" is a more appropriate recording. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:44:38
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Verify if "OPHTHALMIC" is a more appropriate recording. Please update route as appropriate.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:40:06
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4)	21 Sep 2020 20:38:52
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Verify if "OPHTHALMIC" is a more appropriate recording. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:36:49
User entered 'Intraocular (INTRAOCULAR)'	(b) (4), (b) (6)	07 Aug 2020 12:34:32

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'OPHTHALMIC' reason for change:	Victoria Hernandez (b) (4)	21 Sep 2020 20:38:52
Data Entry Error	(b) (4)	
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:34:32

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:55:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
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)	11 Aug 2020 13:42:59
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	07 Aug 2020 12:49:12
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	07 Aug 2020 12:34:32
User entered 'un UNK 2007'	(b) (4), (b) (6)	07 Aug 2020 12:34:32

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 12:34:32

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:34:32

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:08**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:34:32

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:08**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 12:34:32

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 12:34:32



**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 12:34:32

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 12:34:32

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:08

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 20:45:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 20:45:57
Data point term sent to Coder Coding entries removed.	System Victoria Hernandez (b) (4) (b) (4)	21 Sep 2020 20:45:17 21 Sep 2020 20:44:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 18:29:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 18:29:17
Data point term sent to Coder User entered 'Tramadol'	System (b) (4), (b) (6)	07 Aug 2020 12:35:51 07 Aug 2020 12:35:41

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:44:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:35:41

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Please update the indication to reflect the specific anatomical location and type of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate. Otherwise, if used as prophylaxis, update the indication with the medical condition that this medication was trying to prevent (e.g., Thrombosis prophylaxis). Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:45:14
Query 'Per DM CLR: Please update the indication to reflect the specific anatomical location and type of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate. Otherwise, if used as prophylaxis, update the indication with the medical condition that this medication was trying to prevent (e.g., Thrombosis prophylaxis). Review and update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:45:20
User entered 'LEFT KNEE PAIN' reason for change: Data Entry Error	(b) (4)	21 Sep 2020 20:44:57
User opened query 'Per DM CLR: Please update the indication to reflect the specific anatomical location and type of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate. Otherwise, if used as prophylaxis, update the indication with the medical condition that this medication was trying to prevent (e.g., Thrombosis prophylaxis). Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 06:53:06
Query 'Per DM CLR: Per DM CLR: Please update the indication to reflect the specific anatomical location and type of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate. Otherwise, if used as prophylaxis, update the indication with the medical condition that this medication was trying to prevent (e.g., Thrombosis prophylaxis). Review and update eCRF as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 06:52:01

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:08

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per DM CLR: Please update the indication to reflect the specific anatomical location and type of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate. Otherwise, if used as prophylaxis, update the indication with the medical condition that this medication was trying to prevent (e.g., Thrombosis prophylaxis). Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:43:45
User entered 'Pain'	(b) (4), (b) (6)	07 Aug 2020 12:35:41

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 21:36:26
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:45:30
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'UPDATED ' (Site from DM).	Victoria Hernandez (b) (4) (b) (4)	21 Sep 2020 20:45:25
User entered '100' reason for change: Data Entry Error	Victoria Hernandez (b) (4) (b) (4)	21 Sep 2020 20:44:57
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:44:04
User entered '1'	(b) (4), (b) (6)	07 Aug 2020 12:35:41

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 21:36:30
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'mg (mg)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:44:57
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	07 Aug 2020 12:35:41



US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:08

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:35:41

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Aug 2020 12:35:41

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:35:41

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Aug 2020 12:35:41

US3292023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:08**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:35:41

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:55:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
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)	11 Aug 2020 13:43:03
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)	07 Aug 2020 12:48:58
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	07 Aug 2020 12:35:41
User entered 'un UNK 2007'	(b) (4), (b) (6)	07 Aug 2020 12:35:41

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 12:35:41

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:35:41



**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:08**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:35:41

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:08**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 12:35:41

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 12:35:41

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 12:35:41

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 12:35:41

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
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: ERGOCALCIFEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 00:14:10
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 00:14:10
Data point term sent to Coder	System	07 Aug 2020 12:37:51
User entered 'Ergocalciferol'	(b) (4), (b) (6)	07 Aug 2020 12:37:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:45:45
Query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:45:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	21 Sep 2020 20:45:39
User opened query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:31:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:37:39

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:55:08**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Vitamin D deficiency'	(b) (4), (b) (6)	07 Aug 2020 12:37:39



US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '1.25'	(b) (4), (b) (6)	07 Aug 2020 12:37:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Aug 2020 12:37:39

US3292023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:55:08**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:37:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'every week (QS)'	(b) (4), (b) (6)	07 Aug 2020 12:37:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:37:39

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:55:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Aug 2020 12:37:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:37:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
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)	11 Aug 2020 13:43:08
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)	07 Aug 2020 12:48:40
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	07 Aug 2020 12:37:39
User entered 'un UNK 2019'	(b) (4), (b) (6)	07 Aug 2020 12:37:39



**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 12:37:39

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:55:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:37:39

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:55:08**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:37:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:55:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 12:37:39

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:55:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 12:37:39

US3292023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 12:37:39

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	07 Aug 2020 12:37:39

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:08

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 10:34:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 10:34:39
Data point term sent to Coder	System	21 Sep 2020 20:49:24
Coding entries removed.	Victoria Hernandez (b) (4) (b) (4)	21 Sep 2020 20:49:04
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Sep 2020 07:47:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Sep 2020 07:47:47
Data point term sent to Coder	System	11 Sep 2020 21:01:15
User closed query 'DM-Coding: please check spelling and update this term in accordance with your answer.' (Site from System).	System	11 Sep 2020 21:00:29
Query 'DM-Coding: please check spelling and update this term in accordance with your answer.' answered with 'UPDATED' (Site from System).	Victoria Hernandez (b) (4) (b) (4)	11 Sep 2020 21:00:29
User entered 'DOXYCYCLINE' reason for change: Data Entry Error	Victoria Hernandez (b) (4) (b) (4)	11 Sep 2020 21:00:16
User opened query 'DM-Coding: please check spelling and update this term in accordance with your answer.' (Site from System).	Coder Import (b) (4) (b) (4)	17 Aug 2020 08:12:17
Data point term sent to Coder	System	07 Aug 2020 12:41:53
User entered 'Doxycycmono'	(b) (4), (b) (6) (b) (4)	07 Aug 2020 12:41:30



US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:49:04
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 12:41:30

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:08

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is trying to prevent or treat (e.g., NAUSEA prophylaxis). Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 16:10:13
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is trying to prevent or treat (e.g., NAUSEA prophylaxis). Update Con Med eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:49:09
User entered 'DENTAL INFECTION' reason for change: Data Entry Error	(b) (4)	21 Sep 2020 20:49:04
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is trying to prevent or treat (e.g., NAUSEA prophylaxis). Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:29:58
User entered 'Used before dental work'	(b) (4), (b) (6)	07 Aug 2020 12:41:30

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:55:08**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '100'	(b) (4), (b) (6)	07 Aug 2020 12:41:30

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Aug 2020 12:41:30

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:08

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:41:30

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:08

[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 23:03:57
	(b) (4), (b) (6)	04 Nov 2020 21:10:48
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' answered with 'CORRECT PER PATIENT' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:49:24
	(b) (4)	
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:30:09
User entered 'as needed (PRN)'	(b) (4), (b) (6)	07 Aug 2020 12:41:30

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:41:30

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:55:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Aug 2020 12:41:30



US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:41:30

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
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)	11 Aug 2020 13:43:19
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)	07 Aug 2020 12:48:22
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	07 Aug 2020 12:41:30
User entered 'un UNK 2016'	(b) (4), (b) (6)	07 Aug 2020 12:41:30

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 12:41:30

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:08

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Please review and confirm the status of this medication as it is unexpected to be ongoing for a long period of time. Review and update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:50:26
Query 'Per DM CLR: Please review and confirm the status of this medication as it is unexpected to be ongoing for a long period of time. Review and update as appropriate. Otherwise, clarify.' answered with 'ONLY TAKES FOR DENTAL PROCEDURES' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:49:40
User opened query 'Per DM CLR: Please review and confirm the status of this medication as it is unexpected to be ongoing for a long period of time. Review and update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:30:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:41:30

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:41:30

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:55:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 12:41:30

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:55:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 12:41:30

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 12:41:30



**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 12:41:30

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 03:53:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 03:53:51
Data point term sent to Coder Coding entries removed.	System Dawn Killian (b) (4) (b) (4)	28 Oct 2020 19:50:24 28 Oct 2020 19:49:30
User entered 'TRIAMCINOLONE 0.025%' reason for change: Data Entry Error User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\\202003.	Dawn Killian (b) (4) (b) (4) Coder Import (b) (4) (b) (4)	28 Oct 2020 19:49:30 22 Sep 2020 15:08:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 15:08:44
Data point term sent to Coder Coding entries removed.	System Victoria Hernandez (b) (4) (b) (4)	21 Sep 2020 20:51:25 21 Sep 2020 20:51:06
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 23:32:20

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:08

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	10 Aug 2020 23:32:20
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	07 Aug 2020 12:45:54
User entered 'Triamcinolone'	(b) (4), (b) (6)	07 Aug 2020 12:45:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#18) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:33:22
Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#18) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	28 Oct 2020 19:49:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	28 Oct 2020 19:49:30
User opened query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#18) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 09:13:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:45:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Please update the indication to reflect the specific type of RASH. Please reconcile with the Med History eCRFs as appropriate. Otherwise, if used as prophylaxis, update the indication with the medical condition that this medication was trying to prevent (e.g., Thrombosis prophylaxis). Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:51:16
Query 'Per DM CLR: Please update the indication to reflect the specific type of RASH. Please reconcile with the Med History eCRFs as appropriate. Otherwise, if used as prophylaxis, update the indication with the medical condition that this medication was trying to prevent (e.g., Thrombosis prophylaxis). Review and update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:51:14
User entered 'FACIAL ATOPIC DERMATITIS' reason for change: Data Entry Error	(b) (4)	21 Sep 2020 20:51:06
User opened query 'Per DM CLR: Please update the indication to reflect the specific type of RASH. Please reconcile with the Med History eCRFs as appropriate. Otherwise, if used as prophylaxis, update the indication with the medical condition that this medication was trying to prevent (e.g., Thrombosis prophylaxis). Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:45:36
User entered 'Rash to face'	(b) (4), (b) (6)	07 Aug 2020 12:45:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:08

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note 0.025% is a dose strength rather than an actual dosage. Please update the Med Name to include the dose strength (e.g. Triamcinolone 0.025%) and enter the correct dosage form in the Dose & Unit fields (e.g. 1 Application). Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 20:33:27
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
Query 'Per DM CLR: Note 0.025% is a dose strength rather than an actual dosage. Please update the Med Name to include the dose strength (e.g. Triamcinolone 0.025%) and enter the correct dosage form in the Dose & Unit fields (e.g. 1 Application). Update eCRF as appropriate.' answered with 'updaetd' (Site from DM).	Dawn Killian (b) (4)	28 Oct 2020 19:49:41
User entered '1' reason for change: Data Entry Error	Dawn Killian (b) (4)	28 Oct 2020 19:49:30
User opened query 'Per DM CLR: Note 0.025% is a dose strength rather than an actual dosage. Please update the Med Name to include the dose strength (e.g. Triamcinolone 0.025%) and enter the correct dosage form in the Dose & Unit fields (e.g. 1 Application). Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 09:14:16
Query 'Per DM CLR: Note 0.025% is a dose strength rather than an actual dosage. Please update the Med Name to include the dose strength (e.g. Triamcinolone 0.025%) and enter the correct dosage form in the Dose & Unit fields (e.g. 1 Application). Update eCRF as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 09:14:07
User opened query 'Per DM CLR: Note 0.025% is a dose strength rather than an actual dosage. Please update the Med Name to include the dose strength (e.g. Triamcinolone 0.025%) and enter the correct dosage form in the Dose & Unit fields (e.g. 1 Application). Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 09:13:59

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:08

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query ' Per DM CLR: Please note, 0.025 % appears to be a concentration/strength, rather than dosage. Please update the Con Med entry to provide the concentration/strength in the Medication field (e.g., Betamethasone 0.05%) and list the specific dose and unit (e.g. Dose = 1; Unit = Application) within the DOSE and UNIT fields. Update ConMed eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 09:13:59
Query 'Per DM CLR: Please note, 0.025 % appears to be a concentration/strength, rather than dosage. Please update the Con Med entry to provide the concentration/strength in the Medication field (e.g., Betamethasone 0.05%) and list the specific dose and unit (e.g. Dose = 1; Unit = Application) within the DOSE and UNIT fields. Update ConMed eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4) (b) (4)	21 Sep 2020 20:51:19
User opened query 'Per DM CLR: Please note, 0.025 % appears to be a concentration/strength, rather than dosage. Please update the Con Med entry to provide the concentration/strength in the Medication field (e.g., Betamethasone 0.05%) and list the specific dose and unit (e.g. Dose = 1; Unit = Application) within the DOSE and UNIT fields. Update ConMed eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:45:46
User entered '0.025%'	(b) (4), (b) (6)	07 Aug 2020 12:45:34

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:55:08**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Other (OTHER)'	(b) (4), (b) (6)	07 Aug 2020 12:45:34



US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:08

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'application' reason for change: Data Entry Error	Dawn Killian (b) (4)	28 Oct 2020 19:49:30
User entered 'TOPICAL' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:51:06
User entered 'percent'	(b) (4), (b) (6)	07 Aug 2020 12:45:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'as needed (PRN)'	(b) (4), (b) (6)	07 Aug 2020 12:45:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:45:34

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:55:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	07 Aug 2020 12:45:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:45:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
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)	11 Aug 2020 13:43:24
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)	07 Aug 2020 12:48:04
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	07 Aug 2020 12:45:34
User entered 'un UNK 2009'	(b) (4), (b) (6)	07 Aug 2020 12:45:34

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 12:45:34

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:55:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:45:34



US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:45:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:55:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 12:45:34

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:55:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 12:45:34

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 12:45:34

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 12:45:34

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:55:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: CARBOHYDRATES, PRODUCT: GLUCOSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 22:58:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 22:58:24
Data point term sent to Coder	System	07 Aug 2020 12:46:55
User entered 'Glucose tablets'	(b) (4), (b) (6)	07 Aug 2020 12:46:51

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:55:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM). Query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:52:19
User entered 'No (N)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:52:51
User opened query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding ongoing Medical History condition recorded that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4)	21 Sep 2020 04:33:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:46:51

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:08**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Type 1 Diabetes'	(b) (4), (b) (6)	07 Aug 2020 12:46:51



US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:55:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:52:27
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	21 Sep 2020 20:52:55
User entered '4' reason for change: Data Entry Error	(b) (4)	21 Sep 2020 20:52:39
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:33:03
User entered '1'	(b) (4), (b) (6)	07 Aug 2020 12:46:51

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:55:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'g (g)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 20:52:39
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	07 Aug 2020 12:46:51

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:55:08

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:46:51

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:08**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'as needed (PRN)'	(b) (4), (b) (6)	07 Aug 2020 12:46:51

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:55:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:46:51

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Aug 2020 12:46:51

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:08**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:46:51

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:55:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
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)	11 Aug 2020 13:43:30
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)	07 Aug 2020 12:47:52
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	07 Aug 2020 12:46:51
User entered 'un UNK 1999'	(b) (4), (b) (6)	07 Aug 2020 12:46:51



**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 12:46:51

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 12:46:51

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:55:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 12:46:51

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:55:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 12:46:51

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 12:46:51

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 12:46:51

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 12:46:51

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 16:24:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	07 Oct 2020 16:24:21
Data point term sent to Coder	System	07 Oct 2020 16:23:58
Data point term sent to Coder	System	07 Oct 2020 16:22:55
Coding entries removed.	(b) (4), (b) (6)	07 Oct 2020 16:22:52
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 07:56:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	25 Sep 2020 07:56:41
Data point term sent to Coder	System	24 Sep 2020 14:10:11
User entered 'Influenza Vaccine'	Kristy Trevino (b) (4)	24 Sep 2020 14:09:55
	(b) (4)	



US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	24 Sep 2020 14:09:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:08

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please review Indication and update to provide the medical condition that this medication was used to prevent. Please update to reflect Prophylaxis and the medical condition prevented as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:35:46
Query 'Per CDM: Please review Indication and update to provide the medical condition that this medication was used to prevent. Please update to reflect Prophylaxis and the medical condition prevented as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 16:24:10
User entered 'influenza' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 16:23:56
User entered 'influenza prophylaxis' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 16:22:52
User opened query 'Per CDM: Please review Indication and update to provide the medical condition that this medication was used to prevent. Please update to reflect Prophylaxis and the medical condition prevented as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 22:16:31
User entered 'Non study vaccine'	Kristy Trevino (b) (4) (b) (4)	24 Sep 2020 14:09:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '.5'	Kristy Trevino (b) (4) (b) (4)	24 Sep 2020 14:09:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:08

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication (consider mL). Please update the unit as appropriate or provide explanation for alternate unit.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 20:35:50
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication (consider mL). Please update the unit as appropriate or provide explanation for alternate unit.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	28 Oct 2020 19:51:22
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4)	28 Oct 2020 19:50:03
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication (consider mL). Please update the unit as appropriate or provide explanation for alternate unit.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 13:58:05
User entered 'mg (mg)'	Kristy Trevino (b) (4)	24 Sep 2020 14:09:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:08

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Kristy Trevino (b) (4) (b) (4)	24 Sep 2020 14:09:55

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:55:08**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'once (ONCE)'	Kristy Trevino (b) (4) (b) (4)	24 Sep 2020 14:09:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:55:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Kristy Trevino (b) (4) (b) (4)	24 Sep 2020 14:09:55

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:55:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Intramuscular (INTRAMUSCULAR)'	Kristy Trevino (b) (4)	24 Sep 2020 14:09:55



US3292023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:55:08**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Kristy Trevino (b) (4) (b) (4)	24 Sep 2020 14:09:55

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '23 Sep 2020'	Kristy Trevino (b) (4)	24 Sep 2020 14:09:55
	(b) (4)	

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	Kristy Trevino (b) (4) (b) (4)	24 Sep 2020 14:09:55

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:55:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Kristy Trevino (b) (4) (b) (4)	24 Sep 2020 14:09:55

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:55:08**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '23 Sep 2020'	Kristy Trevino (b) (4)	24 Sep 2020 14:09:55
	(b) (4)	

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:55:08**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Kristy Trevino (b) (4) (b) (4)	24 Sep 2020 14:09:55

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:55:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 14:09:55

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 14:09:55



**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 14:09:55

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:55:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE IN WATER - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:00:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:00:23
Data point term sent to Coder	System	03 Nov 2020 23:57:34
User entered 'Dextrose 5% in water'	Antonio Gutierrez (b) (4) (b) (4)	03 Nov 2020 23:56:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:55:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:56:37

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:55:08**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Diabetic Ketoacidosis'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:56:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:55:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '1000'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:56:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:55:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'mL (mL)'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:56:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:55:08

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Antonio Gutierrez (b) (4)	03 Nov 2020 23:56:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:55:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'once (ONCE)'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:56:37



US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:55:08

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Antonio Gutierrez (b) (4)	03 Nov 2020 23:56:37

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:55:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Intravenous (INTRAVENOUS)'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:56:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:55:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Antonio Gutierrez (b) (4)	03 Nov 2020 23:56:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:55:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '22 Oct 2020'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:56:37

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:56:37

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:55:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:56:37

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:55:08**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '22 Oct 2020'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:56:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:55:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:56:37



**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:55:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 23:56:37

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 23:56:37

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 23:56:37

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:55:08

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 12:33:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 12:33:11
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
Data point term sent to Coder	System	03 Nov 2020 23:59:36
User entered 'Insulin Regular 100 units + sodium chloride 0.9%'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:59:05

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:55:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:59:05

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:55:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Diabetic Ketoacidosis'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:59:05

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:55:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '100'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:59:05

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:55:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'mL (mL)'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:59:05



**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:55:08**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Antonio Gutierrez (b) (4)	03 Nov 2020 23:59:05

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:55:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'once (ONCE)'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:59:05

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:55:08

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Antonio Gutierrez (b) (4)	03 Nov 2020 23:59:05

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:55:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Intravenous (INTRAVENOUS)'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:59:05

US3292023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:55:08**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Antonio Gutierrez (b) (4)	03 Nov 2020 23:59:05

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '22 Oct 2020'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:59:05

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:59:05

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:55:08

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:59:05



**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:55:08**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '22 Oct 2020'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:59:05

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:55:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Antonio Gutierrez (b) (4)	03 Nov 2020 23:59:05

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:55:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 23:59:05

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 23:59:05

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 23:59:05

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:55:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN, PRODUCTSYNONYM: INSULIN, REGULAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:14:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:14:20
Data point term sent to Coder	System	04 Nov 2020 00:02:02
User entered 'insulin regular human recomb 100 units/mL'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:01:18

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:55:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:01:18

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:55:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Diabetic Ketoacidosis'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:01:18



**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:55:08**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'UNK'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:01:18

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:55:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Other (OTHER)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:01:18

US3292023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:55:08**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'UNKNOWN'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:01:18

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:55:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'once (ONCE)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:01:18

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:55:08

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Antonio Gutierrez (b) (4)	04 Nov 2020 00:01:18

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:55:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Intravenous (INTRAVENOUS)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:01:18

US3292023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:55:08**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Antonio Gutierrez (b) (4)	04 Nov 2020 00:01:18

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:55:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '22 Oct 2020'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:01:18



US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:55:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:01:18

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:55:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:01:18

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:55:08**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '22 Oct 2020'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:01:18

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:55:08**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:01:18

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:55:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 00:01:18

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 00:01:18

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 00:01:18

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:55:08

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM BICARBONATE;SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 07:58:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 07:58:11
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
Data point term sent to Coder	System	04 Nov 2020 00:06:03
User entered 'Sodium Chloride 0.45% + Sodium Bicarbonate 8.4% 50 mEq'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:05:28



US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:55:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:05:28

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:55:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Diabetic Ketoacidosis'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:05:28

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:55:08**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '1000'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:05:28

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:55:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'mL (mL)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:05:28

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:55:08

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Antonio Gutierrez (b) (4)	04 Nov 2020 00:05:28

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:55:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'once (ONCE)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:05:28

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:55:08

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Antonio Gutierrez (b) (4)	04 Nov 2020 00:05:28

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:55:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Intravenous (INTRAVENOUS)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:05:28



**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:55:08**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Antonio Gutierrez (b) (4)	04 Nov 2020 00:05:28

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:55:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '22 Oct 2020'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:05:28

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:55:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:05:28

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:55:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:05:28

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:55:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '22 Oct 2020'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:05:28

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:55:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:05:28

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:55:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 00:05:28

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 00:05:28



**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 00:05:28

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:55:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:29:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:29:16
Data point term sent to Coder	System	04 Nov 2020 00:08:04
User entered 'Sodium Chloride 0.9%'	Antonio Gutierrez (b) (4) (b) (4)	04 Nov 2020 00:07:26

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:55:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:07:26

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:55:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Diabetic Ketoacidosis'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:07:26

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:55:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '2000'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:07:26

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:55:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'mL (mL)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:07:26

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:55:08

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Antonio Gutierrez (b) (4)	04 Nov 2020 00:07:26

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:55:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'once (ONCE)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:07:26



US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:55:08

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Antonio Gutierrez (b) (4)	04 Nov 2020 00:07:26

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 26 Nov 2020 10:55:08**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'Intravenous (INTRAVENOUS)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:07:26

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:55:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered empty.	Antonio Gutierrez (b) (4)	04 Nov 2020 00:07:26

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:55:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '22 Oct 2020'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:07:26

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:55:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '0'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:07:26

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 26 Nov 2020 10:55:08**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:07:26

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:55:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered '22 Oct 2020'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:07:26

US3292023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:55:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:10:48
User entered 'No (N)'	Antonio Gutierrez (b) (4)	04 Nov 2020 00:07:26



**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 26 Nov 2020 10:55:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 00:07:26

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 00:07:26

**US3292023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 26 Nov 2020 10:55:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 00:07:26

**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:08**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'USA-US072-2020-MRNA-1273-P301000007'	System	28 Oct 2020 17:21:27

**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:08**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'Yes (Y)'	System	28 Oct 2020 17:21:27

**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:08**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'No (N)'	System	28 Oct 2020 17:21:27

**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:08**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'No (N)'	System	28 Oct 2020 17:21:27

**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'Yes (Y)'	System	28 Oct 2020 17:21:27



**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:08**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'No (N)'	System	28 Oct 2020 17:21:27

**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:08**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'No (N)'	System	28 Oct 2020 17:21:27

**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:08**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'No (N)'	System	28 Oct 2020 17:21:27

**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:08**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'Douglas'	System	28 Oct 2020 17:21:27

**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:08**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'Denham'	System	28 Oct 2020 17:21:27

**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:08**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered '7940 Floyd Curl Drive'	System	28 Oct 2020 17:21:27

**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:08**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'San Antonio'	System	28 Oct 2020 17:21:27

**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:08**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered '78229'	System	28 Oct 2020 17:21:27



**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:08**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
User entered 'US'	System	28 Oct 2020 17:21:49

**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:08**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Oct 2020 17:21:49

**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:08**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'USA-US072-2020-MRNA-1273-P301000007'	System	28 Oct 2020 17:21:27

**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:08**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'Yes (Y)'	System	28 Oct 2020 17:21:27

**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:08**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'No (N)'	System	28 Oct 2020 17:21:27

**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:08**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'No (N)'	System	28 Oct 2020 17:21:27

**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'Yes (Y)'	System	28 Oct 2020 17:21:27

**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:08**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'No (N)'	System	28 Oct 2020 17:21:27



**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:08**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'No (N)'	System	28 Oct 2020 17:21:27

**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:08**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'No (N)'	System	28 Oct 2020 17:21:27

**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:08**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'Douglas'	System	28 Oct 2020 17:21:27

**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:08**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'Denham'	System	28 Oct 2020 17:21:27

**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:08**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered '7940 Floyd Curl Drive'	System	28 Oct 2020 17:21:27

**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:08**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered 'San Antonio'	System	28 Oct 2020 17:21:27

**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:08**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:21:43
User entered '78229'	System	28 Oct 2020 17:21:27

**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:08**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
User entered 'US'	System	28 Oct 2020 17:21:49



**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:55:08**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Oct 2020 17:21:49

**US3292023**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (1)**

**Generated On: 26 Nov 2020 10:55:08**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
User entered '28/Oct/2020 13:21'	System	28 Oct 2020 17:21:49

US3292023

Folder: SAE USA-US072-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:55:08

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:06:07
User entered 'I'	(b) (4), (b) (6)	28 Oct 2020 17:21:49