

US3292172 (Prod: Clinical Trials of Texas, Inc)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:26:50

All time stamps listed in this document are displayed in GMT

US3292172

Form: Participant Creation

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

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[Participant ID](#)

US3292172

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

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US3292172

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Date of Birth (MMM yyyy)	(b) (6) 1967
Age	53
Age Units	YEARS
Age (Derived)	53
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Date of Informed Consent ( <i>dd MMM yyyy</i> )	13 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 19:56:42

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 22 Feb 2021 19:56:42

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



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Condition	BREAST REDUCTION
Start date (dd MMM yyyy)	UN UNK 1987
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 1987
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1987
Start Year (derived)	1987
Stop Month and Year (derived)	JAN 1987
Stop Year (derived)	1987

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Condition	C-SECTION
Start date (dd MMM yyyy)	UN UNK 1992
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 1992
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	JAN 1992
Stop Year (derived)	1992

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Condition	LEFT KIDNEY DONATION SURGERY
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Condition	RIGHT ROTATOR CUFF INJURY
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

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



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Condition	LEFT ROTATOR CUFF INJURY
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Condition	LEFT ROTATOR CUFF REPAIR
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Condition	VAGINAL DELIVERY
Start date (dd MMM yyyy)	UN UNK 1997
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 1997
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1997
Start Year (derived)	1997
Stop Month and Year (derived)	JAN 1997
Stop Year (derived)	1997

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Condition	RIGHT FOOT OSTEOPHYTES
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Condition	RIGHT FOOT OSTEOPHYTES REMOVAL
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Condition	BUNION REMOVAL
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

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Condition	BUNIONECTOMY
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

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Condition	BILATERAL DECREASED VISUAL ACUITY
Start date (dd MMM yyyy)	UN UNK 1983
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 1983
Start Year (derived)	1983
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Condition	INTERMITTENT HEADACHE
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Condition	POST MENOPAUSAL
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)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	15:17 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 15:17
Height (xxx.x)	161.6 cm
Weight (xxx.x)	93.9 kg
BMI (xxx.x)	35.95695 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 19:56:42

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 22 Feb 2021 19:56:42

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Date of assessment (dd MMM yyyy) 13 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

If No, what is the reason? Surgically sterile ☐  
Post-menopausal ☒  
Partner medically sterile ☐  
Not reached age of Menarche ☐  
Other ☐

If Partner medically sterile or Other, specify \_\_\_\_\_

If Surgically sterile, date of surgery (dd MMM yyyy) \_\_\_\_\_

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2019

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 19:56:42

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 19:56:42

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<b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
<b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)	False
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	False
<b>Resides in a single family home</b> (i.e., detached housing)	True
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 19:57:45

Generated On: 09 Jun 2021 16:26:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1



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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 22 Feb 2021 19:57:45

Generated On: 09 Jun 2021 16:26:50

What was the date of randomization? (dd MMM yyyy) 13 AUG 2020

What was the participant's randomization number? 104156

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☐

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Feb 2021 19:57:45

Generated On: 09 Jun 2021 16:26:50

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 19:57:45

Generated On: 09 Jun 2021 16:26:50

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	15:17 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 15:17
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 19:57:45

Generated On: 09 Jun 2021 16:26:50

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	17:56 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 17:56
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 19:57:45

Generated On: 09 Jun 2021 16:26:50

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 19:57:45

Generated On: 09 Jun 2021 16:26:50

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 13 AUG 2020

What was the treatment time? (00:00-23:59) 17:20 (24 HR)

Treatment Date and Time (derived) 13 AUG 2020 17:20

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 19:57:45

Generated On: 09 Jun 2021 16:26:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 AUG 2020
Collection time (00:00-23:59)	15:26 (24 HR)
Collection date and time (derived)	13 AUG 2020 15:26

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Collection date (dd MMM yyyy)			13 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:47	13 AUG 2020 15:47
Nasopharyngeal Swab 2	No		



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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:57:45

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Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

13 AUG 2020 18:00

PC Open Date & Time

13 AUG 2020 17:40

PC Close Date & Time

13 AUG 2020 20:10

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 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	13 AUG 2020 21:07
PC Open Date & Time	13 AUG 2020 21:05
PC Close Date & Time	14 AUG 2020 11:59

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 22:12

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

15 AUG 2020 20:30

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 21:05

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **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

17 AUG 2020 20:25

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 04:45

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59



US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 7

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

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

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

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

19 AUG 2020 21:31

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 18:00

PC Open Date & Time

13 AUG 2020 17:40

PC Close Date & Time

13 AUG 2020 20:10

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 21:08

PC Open Date & Time

13 AUG 2020 21:05

PC Close Date & Time

14 AUG 2020 11:59

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 22:12

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 20:30

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 21:05

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 20:25

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 04:45

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59



US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 21:31

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 18:01
PC Open Date & Time	13 AUG 2020 17:40
PC Close Date & Time	13 AUG 2020 20:10

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some

interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 21:08
PC Open Date & Time	13 AUG 2020 21:05
PC Close Date & Time	14 AUG 2020 11:59

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:26:50

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 22:12
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)



US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:26:50

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 20:31
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:26:50

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 21:06
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:26:50

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 20:26
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:26:50

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 04:45
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:26:50

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 21:31
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3292172

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292172

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292172

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292172

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292172

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292172

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292172

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 19:57:45

Generated On: 09 Jun 2021 16:26:50

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



US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 19:57:45

Generated On: 09 Jun 2021 16:26:50

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	08:15 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 08:15
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG

US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 19:57:45

Generated On: 09 Jun 2021 16:26:50

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	10:04 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 10:04
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)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3292172

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 19:57:45

Generated On: 09 Jun 2021 16:26:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3292172

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 19:57:45

Generated On: 09 Jun 2021 16:26:50

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 10 SEP 2020

What was the treatment time? (00:00-23:59) 09:22 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 09:22

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

What was the frequency of the study treatment dosing? ONCE

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

US3292172

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 19:57:45

Generated On: 09 Jun 2021 16:26:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 SEP 2020
Collection time (00:00-23:59)	09:27 (24 HR)
Collection date and time (derived)	10 SEP 2020 09:27

US3292172

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 19:57:45

Generated On: 09 Jun 2021 16:26:50

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:37	10 SEP 2020 08:37
Nasopharyngeal Swab 2	No		

US3292172

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:57:45

Generated On: 09 Jun 2021 16:26:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐  
No ☒

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

PC Time Stamp 10 SEP 2020 10:04

PC Open Date & Time 10 SEP 2020 09:42

PC Close Date & Time 10 SEP 2020 12:12



US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	10 SEP 2020 21:32
PC Open Date & Time	10 SEP 2020 13:07
PC Close Date & Time	11 SEP 2020 11:59

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	99.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	11 SEP 2020 19:37
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

12 SEP 2020 23:07

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

13 SEP 2020 21:12

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **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

15 SEP 2020 05:23

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

16 SEP 2020 06:16

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 7

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

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

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

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

17 SEP 2020 06:00

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 10:00

PC Open Date & Time

10 SEP 2020 09:42

PC Close Date & Time

10 SEP 2020 12:12



US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 21:31

PC Open Date & Time

10 SEP 2020 13:07

PC Close Date & Time

11 SEP 2020 11:59

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 19:37

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 23:08

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 21:12

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 05:23

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 06:16

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 06:00

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐



US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 10:00
PC Open Date & Time	10 SEP 2020 09:42
PC Close Date & Time	10 SEP 2020 12:12

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

- None ☐
- No interference with activity ☒
- Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐
- Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

- None ☐
- No interference with activity ☒
- Some interference with activity ☐
- Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

- None ☐
- No interference with activity ☐
- Some interference with activity ☒
- Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

- None ☐
- No interference with activity ☒
- Some interference with activity ☐
- Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

- None ☒
- No interference with activity or  
1-2 episodes/24 hours ☐
- Some interference with activity  
or >2 episodes/24 hours ☐
- Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

- None ☒
- No interference with activity ☐
- Some interference with activity  
not requiring medical attention ☐
- Prevents daily activity and  
requires medical attention ☐

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 21:31
PC Open Date & Time	10 SEP 2020 13:07
PC Close Date & Time	11 SEP 2020 11:59

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

No interference with activity or  
1-2 episodes/24 hours ☒

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☒

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:26:50

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 19:38
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

109 of 1902

EAB) (1725)

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:26:50

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 23:08
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

111 of 1902



US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:26:50

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

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:26:50

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 05:23
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:26:50

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 06:17
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

117 of 1902

EAB) (1725)

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:26:50

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 06:00
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3292172

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

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*



US3292172

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292172

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

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*

US3292172

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292172

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292172

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292172

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 19:57:45

Generated On: 09 Jun 2021 16:26:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3292172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 19:57:45

Generated On: 09 Jun 2021 16:26:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 OCT 2020
Time of assessment (00:00-23:59)	07:57 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 07:57
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3292172

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 19:57:45

Generated On: 09 Jun 2021 16:26:50

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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



US3292172

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 19:57:45

Generated On: 09 Jun 2021 16:26:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 OCT 2020
Collection time (00:00-23:59)	08:10 (24 HR)
Collection date and time (derived)	8 OCT 2020 08:10

US3292172

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:57:45

Generated On: 09 Jun 2021 16:26:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 OCT 2020 08:41:21
Patient Cloud Open Date & Time	13 OCT 2020 00:01
Patient Cloud Close Date & Time	17 OCT 2020 23:59

US3292172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 OCT 2020 21:04:52

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3292172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 OCT 2020 12:00:38

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3292172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 NOV 2020 20:23:50
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3292172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 NOV 2020 10:10:33
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 103

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

No ☒

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

21 NOV 2020 10:08:54

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59



US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	28 NOV 2020 11:26:35
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 11:38:15
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 DEC 2020 07:01:16
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 131

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

No ☒

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

19 DEC 2020 05:08:35

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 07:25:57

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 145

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

No ☒

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 JAN 2021 12:01:10

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 152

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

No ☒

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 JAN 2021 12:00:45

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 JAN 2021 12:02:53
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59



US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

<b>TIMEPOINT</b>	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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 JAN 2021 13:39:27
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 173

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

No ☒

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

01 FEB 2021 12:01:06

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 FEB 2021 10:23:37
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

<b>TIMEPOINT</b>	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 14:18:50
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 194

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

No ☒

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

21 FEB 2021 06:32:26

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

<b>TIMEPOINT</b>	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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAR 2021 15:16:11
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 208

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

No ☒

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

09 MAR 2021 12:34:41

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	15 MAR 2021 05:13:05
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59



US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

<b>TIMEPOINT</b>	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 MAR 2021 19:29:50
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	27 MAR 2021 09:38:16
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	07 APR 2021 09:18:21
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 243

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

No ☒

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

12 APR 2021 12:00:33

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

<b>TIMEPOINT</b>	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 APR 2021 12:00:52
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 257

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

No ☒

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 APR 2021 08:02:47

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 264

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

No ☒

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

03 MAY 2021 12:00:37

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>



**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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29 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JUN 2021 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 299

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



**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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05 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 JUN 2021 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

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

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 327

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



**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUL 2021 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 362

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

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2021 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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14 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 AUG 2021 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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21 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2021 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2021 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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04 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 SEP 2021 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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11 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 SEP 2021 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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02 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 OCT 2021 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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09 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 OCT 2021 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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16 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 OCT 2021 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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23 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 OCT 2021 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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30 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 NOV 2021 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

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

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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20 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 NOV 2021 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 474

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

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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27 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 DEC 2021 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

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

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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04 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 DEC 2021 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

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

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 DEC 2021 23:59
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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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15 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 JAN 2022 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 530

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

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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22 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JAN 2022 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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29 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 FEB 2022 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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05 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 FEB 2022 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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12 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 FEB 2022 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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19 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 FEB 2022 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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26 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 MAR 2022 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

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 ☐

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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05 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAR 2022 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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12 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAR 2022 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 586

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

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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19 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAR 2022 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 593
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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26 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAR 2022 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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02 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 APR 2022 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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16 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 APR 2022 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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23 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 APR 2022 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 628

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

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 635

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



**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2022 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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14 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2022 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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21 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2022 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 663

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



**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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04 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 JUN 2022 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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11 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 JUN 2022 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 677

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

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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18 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 JUN 2022 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

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

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 698

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

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 705

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

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

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27 JUL 2022 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 719

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



**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

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03 AUG 2022 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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13 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 AUG 2022 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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20 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 AUG 2022 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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27 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 AUG 2022 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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03 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 SEP 2022 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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10 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 SEP 2022 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 775

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



**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

<a href="#">Patient Cloud Open Date &amp; Time</a>	24 SEP 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 SEP 2022 23:59
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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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08 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 OCT 2022 23:59

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US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

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

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[Patient Cloud Open Date & Time](#)

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15 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 OCT 2022 23:59

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US3292172

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:26:50

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 15:16:25



US3292172

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 NOV 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

3 ATTEMPTEDS WITH NO  
ANSWER

*If Contact Not Made, please provide Comments*

US3292172

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292172

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292172

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292172

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 JAN 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

CALLED PATIENT THREE  
TIMES; NO ANSWER.

*If Contact Not Made, please provide Comments*

US3292172

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292172

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292172

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:56:42

Generated On: 09 Jun 2021 16:26:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3292172

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:06:00

Generated On: 09 Jun 2021 16:26:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	8 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3292172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:06:00

Generated On: 09 Jun 2021 16:26:50

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3292172

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:06:00

Generated On: 09 Jun 2021 16:26:50

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3292172

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:06:00

Generated On: 09 Jun 2021 16:26:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 MAR 2021
Collection time (00:00-23:59)	09:49 (24 HR)
Collection date and time (derived)	8 MAR 2021 09:49

US3292172

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:06:00

Generated On: 09 Jun 2021 16:26:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292172

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:06:00

Generated On: 09 Jun 2021 16:26:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292172

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:06:00

Generated On: 09 Jun 2021 16:26:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3292172**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:26:50**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



**US3292172**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:26:50**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3292172

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:26:50

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

**US3292172**

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

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

**Generated On: 09 Jun 2021 16:26:50**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3292172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:06:00

Generated On: 09 Jun 2021 16:26:50

Was this visit performed? Yes ☐  
No ☒

Visit date (dd MMM yyyy) \_\_\_\_\_

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

Folder OID UNBLND\_DECIDE

US3292172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 14:06:00

Generated On: 09 Jun 2021 16:26:50

Date of updated informed consent (dd MMM yyyy) 8 MAR 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 15 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3292172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:06:00

Generated On: 09 Jun 2021 16:26:50

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3292172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Apr 2021 14:05:59

Generated On: 09 Jun 2021 16:26:50

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00 - 23:59)

Collection Date and Time (derived)

US3292172

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Apr 2021 14:05:59

Generated On: 09 Jun 2021 16:26:50

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Did the participant experience any adverse events?

Yes ☐

No ☒

---

If Yes, enter details on the Adverse Events form.

---



US3292172

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 13:36:41

Generated On: 09 Jun 2021 16:26:50

AEID	USA-US072-2021-MRNA-1273-P30 1000020
Adverse event	UTERINE CANCER
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)	19 FEB 2021
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)	07 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3292172

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 13:36:41

Generated On: 09 Jun 2021 16:26:50

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3292172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Apr 2021 15:47:50

Generated On: 09 Jun 2021 16:26:50

---

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

Yes ☒

No ☐

---

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

---

US3292172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 15:47:50

Generated On: 09 Jun 2021 16:26:50

Name of Medication ZYRTEC-D

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGY

Dose per administration 120/5

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3292172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 15:47:50

Generated On: 09 Jun 2021 16:26:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3292172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 15:47:50

Generated On: 09 Jun 2021 16:26:50

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

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 ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3292172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 15:47:50

Generated On: 09 Jun 2021 16:26:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1985
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"/>

US3292172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 15:47:50

Generated On: 09 Jun 2021 16:26:50

Name of Medication	TRAMADOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	PAIN
Dose per administration	50
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input 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"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3292172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 15:47:50

Generated On: 09 Jun 2021 16:26:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	5 APR 2021	
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"/>

US3292172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 15:47:50

Generated On: 09 Jun 2021 16:26:50

Name of Medication TYLENOL

Prophylaxis Yes ☒  
No ☐

Indication REACTOGENICITY - PAIN AT  
INJECTION SITE

Dose per administration 500

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3292172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 15:47:50

Generated On: 09 Jun 2021 16:26:50

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 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)		11 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3292172

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Apr 2021 14:05:59

Generated On: 09 Jun 2021 16:26:50

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3292172

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 22 Apr 2021 15:47:50

Generated On: 09 Jun 2021 16:26:50

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
19 FEB 2021	PAP SMEAR	Diagnostic	
5 APR 2021	TOTAL HYSTERECTOMY	Adverse Event	

US3292172

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:26:50

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

US3292172

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:26:50

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3292172

Folder: SAE USA-US072-2021-MRNA-1273-P301000020

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 13:36:41

Generated On: 09 Jun 2021 16:26:50

SAEID	USA-US072-2021-MRNA-1273-P301000020
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	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



US3292172

Folder: SAE USA-US072-2021-MRNA-1273-P301000020

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 13:36:41

Generated On: 09 Jun 2021 16:26:50

SAEID	USA-US072-2021-MRNA-1273-P301000020
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	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)	27/APR/2021 08:38
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3292172 (Prod: Clinical Trials of Texas, Inc)

**US3292172**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 16:26:50**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:15:43
User entered 'US3292172'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 21:54:17

US3292172

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:26:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:40:07

US3292172

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 21:54:18

US3292172

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Aug 2020 02:40:07

US3292172

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:26:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'SCRN'	System	16 Aug 2020 02:40:07

US3292172

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:26:50

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered (b) (6) 1967'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 21:54:19



US3292172

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:26:50

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '53'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:40:26

US3292172

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:26:50

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'YEARS'	System	16 Aug 2020 02:40:26

US3292172

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:26:50

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '53'	System	13 Aug 2020 22:51:15

US3292172

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:26:50

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:40:26

US3292172

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:26:50

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	16 Aug 2020 02:40:26

US3292172

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:26:50

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'l'	(b) (4), (b) (6)	16 Aug 2020 02:40:26

US3292172

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:26:50

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:40:26

**US3292172**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:26:50**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:40:26



US3292172

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:26:50

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:40:26

**US3292172**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:26:50**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:40:26

**US3292172**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:26:50**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:40:26

**US3292172**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:26:50**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:40:26

**US3292172**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:26:50**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:40:26

US3292172

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:26:50

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:40:26

US3292172

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:26:50

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '13 Aug 2020'	(b) (4) Nathan Cortez (b) (4)	13 Aug 2020 22:51:15

US3292172

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Aug 2020'	System	13 Aug 2020 22:51:15



US3292172

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '2020'	System	13 Aug 2020 22:51:15

US3292172

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:26:50

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Amendment 2 (2)'	(b) (4) Nathan Cortez (b) (4)	13 Aug 2020 22:51:15

US3292172

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	13 Aug 2020 22:51:15

**US3292172**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:26:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty.	(b) (4) Nathan Cortez (b) (4)	13 Aug 2020 22:51:15

US3292172

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:26:50

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty.	(b) (4) Nathan Cortez (b) (4)	13 Aug 2020 22:51:15

US3292172

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:26:50

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	13 Aug 2020 22:51:15

US3292172

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:26:50

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 21:54:18

US3292172

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:26:50

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'l'	System	13 Aug 2020 22:51:19



US3292172

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	13 Aug 2020 22:51:19

US3292172

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:26:50

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 02:40:42

US3292172

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:26:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	18 Aug 2020 00:04:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 00:04:15
Data point term sent to Coder	System	16 Aug 2020 02:42:02
User entered 'Lidocaine allergy'	(b) (4), (b) (6)	16 Aug 2020 02:41:32

US3292172

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:41:32

US3292172

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:26:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:41:32

US3292172

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:26:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 02:41:32

**US3292172**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:26:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 02:41:32

US3292172

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:26:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:41:32



US3292172

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 2015'	System	16 Aug 2020 02:41:32

US3292172

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:26:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '2015'	System	16 Aug 2020 02:41:32

US3292172

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered empty.	System	16 Aug 2020 02:41:32

US3292172

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered empty.	System	16 Aug 2020 02:41:32

US3292172

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:26:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
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)	16 Aug 2020 02:43:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Aug 2020 02:43:20
Data point term sent to Coder	System	16 Aug 2020 02:43:03
User entered 'Seasonal allergy'	(b) (4), (b) (6)	16 Aug 2020 02:42:18

US3292172

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 1990'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:42:18

US3292172

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:26:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:42:18

**US3292172**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:26:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 02:42:18



US3292172

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 02:42:18

**US3292172**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:26:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:42:18

US3292172

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 1990'	System	16 Aug 2020 02:42:18

US3292172

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:26:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '1990'	System	16 Aug 2020 02:42:18

US3292172

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered empty.	System	16 Aug 2020 02:42:18

US3292172

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered empty.	System	16 Aug 2020 02:42:18

US3292172

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:26:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Breast therapeutic procedures NEC, PT: Mammoplasty, LLT: Breast reduction - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Aug 2020 02:48:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Aug 2020 02:48:19
Data point term sent to Coder	System	16 Aug 2020 02:48:03
User entered 'Breast Reduction'	(b) (4), (b) (6)	16 Aug 2020 02:47:05

US3292172

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 1987'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:47:05



US3292172

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:26:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:47:05

US3292172

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:26:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 02:47:05

US3292172

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 1987'	(b) (4), (b) (6)	16 Aug 2020 02:47:05

US3292172

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:26:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:47:05

US3292172

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 1987'	System	16 Aug 2020 02:47:05

US3292172

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:26:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '1987'	System	16 Aug 2020 02:47:05

US3292172

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 1987'	System	16 Aug 2020 02:47:05

US3292172

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '1987'	System	16 Aug 2020 02:47:05



US3292172

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:26:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: C-section - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Aug 2020 02:48:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Aug 2020 02:48:19
Data point term sent to Coder	System	16 Aug 2020 02:48:03
User entered 'c-section'	(b) (4), (b) (6)	16 Aug 2020 02:47:25

US3292172

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 1992'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:47:25

**US3292172**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:26:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:47:25

US3292172

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:26:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:47:25

US3292172

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 1992'	(b) (4), (b) (6)	16 Aug 2020 02:47:25

US3292172

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:26:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:47:25

US3292172

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 1992'	System	16 Aug 2020 02:47:25

US3292172

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:26:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '1992'	System	16 Aug 2020 02:47:25



US3292172

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 1992'	System	16 Aug 2020 02:47:25

US3292172

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '1992'	System	16 Aug 2020 02:47:25

US3292172

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:26:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User coded data point as SOC: Social circumstances, HLT: Lifestyle issues, HLT: Social issues NEC, PT: Organ donor, LLT: Kidney donor - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Aug 2020 08:17:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 08:17:18
Data point term sent to Coder	System	16 Aug 2020 02:49:03
User entered 'LEFT KIDNEY DONATION surgery' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Aug 2020 02:48:44
User entered 'Left kidney donation'		16 Aug 2020 02:48:23

US3292172

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:48:23

**US3292172**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:26:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:48:23

US3292172

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:26:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:48:23

US3292172

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 2010'	(b) (4), (b) (6)	16 Aug 2020 02:48:23

US3292172

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:26:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:48:23



US3292172

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 2010'	System	16 Aug 2020 02:48:23

US3292172

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:26:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '2010'	System	16 Aug 2020 02:48:23

US3292172

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 2010'	System	16 Aug 2020 02:48:23

US3292172

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '2010'	System	16 Aug 2020 02:48:23

US3292172

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:26:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Tendon injury, LLT: Achilles tendon injury - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Aug 2020 05:45:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Aug 2020 05:45:15
Data point term sent to Coder	System	16 Aug 2020 02:52:04
User entered 'Left Achilles tendon damage'	(b) (4), (b) (6)	16 Aug 2020 02:51:21

US3292172

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 2013'	(b) (4), (b) (6)	16 Aug 2020 02:51:21

US3292172

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:26:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:51:21

US3292172

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:26:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 02:51:21



US3292172

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 2013'	(b) (4), (b) (6)	16 Aug 2020 02:51:21

US3292172

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:26:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:51:21

US3292172

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 2013'	System	16 Aug 2020 02:51:21

US3292172

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:26:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '2013'	System	16 Aug 2020 02:51:21

US3292172

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 2013'	System	16 Aug 2020 02:51:21

US3292172

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '2013'	System	16 Aug 2020 02:51:21

US3292172

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:26:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Soft tissue therapeutic procedures, HLT: Tendon therapeutic procedures, PT: Tenoplasty, LLT: Achilles tendon repair - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	17 Aug 2020 23:41:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 23:41:14
Data point term sent to Coder	System	16 Aug 2020 02:53:04
User entered 'Left achilles tendon surgery'	(b) (4), (b) (6)	16 Aug 2020 02:52:08

US3292172

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 2013'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:52:08



US3292172

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:26:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:52:08

US3292172

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:26:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 02:52:08

US3292172

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 2013'	(b) (4), (b) (6)	16 Aug 2020 02:52:08

US3292172

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:26:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:52:08

US3292172

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 2013'	System	16 Aug 2020 02:52:08

US3292172

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:26:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '2013'	System	16 Aug 2020 02:52:08

US3292172

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 2013'	System	16 Aug 2020 02:52:08

US3292172

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '2013'	System	16 Aug 2020 02:52:08



US3292172

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:26:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Rotator cuff injury - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	16 Aug 2020 02:55:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Aug 2020 02:55:20
Data point term sent to Coder	System	16 Aug 2020 02:55:05
User entered 'Right Rotator cuff injury'	(b) (4), (b) (6)	16 Aug 2020 02:54:07

US3292172

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:54:07

US3292172

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:26:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:54:07

US3292172

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:26:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 02:54:07

US3292172

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 2010'	(b) (4), (b) (6)	16 Aug 2020 02:54:07

US3292172

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:26:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:54:07

US3292172

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 2010'	System	16 Aug 2020 02:54:07

US3292172

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:26:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '2010'	System	16 Aug 2020 02:54:07



US3292172

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 2010'	System	16 Aug 2020 02:54:07

US3292172

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '2010'	System	16 Aug 2020 02:54:07

US3292172

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:26:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Aug 2020 02:55:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Aug 2020 02:55:20
Data point term sent to Coder	System	16 Aug 2020 02:55:05
User entered 'Right rotator cuff repair'	(b) (4), (b) (6)	16 Aug 2020 02:54:33

US3292172

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 2013'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:54:33

US3292172

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:26:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:54:33

**US3292172**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:26:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 02:54:33

US3292172

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 2013'	(b) (4), (b) (6)	16 Aug 2020 02:54:33

US3292172

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:26:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:54:33



US3292172

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 2013'	System	16 Aug 2020 02:54:33

US3292172

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:26:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '2013'	System	16 Aug 2020 02:54:33

US3292172

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 2013'	System	16 Aug 2020 02:54:33

US3292172

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '2013'	System	16 Aug 2020 02:54:33

US3292172

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:26:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Rotator cuff injury - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Aug 2020 02:55:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Aug 2020 02:55:21
Data point term sent to Coder	System	16 Aug 2020 02:55:05
User entered 'Left rotator cuff injury'	(b) (4), (b) (6)	16 Aug 2020 02:55:01

US3292172

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 2014'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:55:01

US3292172

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:26:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:55:01

US3292172

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:26:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 02:55:01



US3292172

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 2014'	(b) (4), (b) (6)	16 Aug 2020 02:55:01

US3292172

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:26:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:55:01

US3292172

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:26:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 2014'	System	16 Aug 2020 02:55:01

US3292172

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:26:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '2014'	System	16 Aug 2020 02:55:01

**US3292172**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:26:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 2014'	System	16 Aug 2020 02:55:01

US3292172

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '2014'	System	16 Aug 2020 02:55:01

US3292172

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:26:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Aug 2020 02:56:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Aug 2020 02:56:20
Data point term sent to Coder	System	16 Aug 2020 02:56:05
User entered 'Left rotator cuff repair'	(b) (4), (b) (6)	16 Aug 2020 02:55:31

US3292172

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 2014'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:55:31



US3292172

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:26:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:55:31

**US3292172**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:26:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 02:55:31

US3292172

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 2014'	(b) (4), (b) (6)	16 Aug 2020 02:55:31

US3292172

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:26:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:55:31

US3292172

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:26:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 2014'	System	16 Aug 2020 02:55:31

US3292172

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:26:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '2014'	System	16 Aug 2020 02:55:31

US3292172

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 2014'	System	16 Aug 2020 02:55:31

US3292172

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '2014'	System	16 Aug 2020 02:55:31



US3292172

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:26:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLGT: Pregnancy, labour, delivery and postpartum conditions, HLT: Normal pregnancy, labour and delivery, PT: Delivery, LLT: Vaginal delivery - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Aug 2020 02:56:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Aug 2020 02:56:20
Data point term sent to Coder	System	16 Aug 2020 02:56:05
User entered 'Vaginal delivery'	(b) (4), (b) (6)	16 Aug 2020 02:55:53

US3292172

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 1997'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:55:53

US3292172

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:26:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:55:53

US3292172

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:26:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 02:55:53

US3292172

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 1997'	(b) (4), (b) (6)	16 Aug 2020 02:55:53

US3292172

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:26:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:55:53

US3292172

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 1997'	System	16 Aug 2020 02:55:53

US3292172

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:26:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '1997'	System	16 Aug 2020 02:55:53



US3292172

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 1997'	System	16 Aug 2020 02:55:53

US3292172

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '1997'	System	16 Aug 2020 02:55:53

US3292172

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:26:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Bone disorders NEC, PT: Exostosis, LLT: Osteophytosis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Aug 2020 06:36:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Aug 2020 06:36:07
Data point term sent to Coder	System	16 Aug 2020 02:58:07
User entered 'Right foot osteophytes'	(b) (4), (b) (6)	16 Aug 2020 02:57:33

US3292172

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 2016'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:57:33

US3292172

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:26:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:57:33

**US3292172**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:26:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 02:57:33

US3292172

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 2016'	(b) (4), (b) (6)	16 Aug 2020 02:57:33

US3292172

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:26:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:57:33



US3292172

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 2016'	System	16 Aug 2020 02:57:33

US3292172

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:26:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '2016'	System	16 Aug 2020 02:57:33

US3292172

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 2016'	System	16 Aug 2020 02:57:33

US3292172

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '2016'	System	16 Aug 2020 02:57:33

US3292172

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:26:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Bone therapeutic procedures NEC, PT: Bone lesion excision, LLT: Bone spur removal - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	18 Nov 2020 10:00:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 10:00:02
Data point term sent to Coder	System	16 Aug 2020 02:58:06
User entered 'right foot osteophytes removal'	(b) (4), (b) (6)	16 Aug 2020 02:58:05

US3292172

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 2016'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:58:05

US3292172

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:26:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:58:05

**US3292172**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:26:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 02:58:05



US3292172

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 2016'	(b) (4), (b) (6)	16 Aug 2020 02:58:05

US3292172

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:26:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:58:05

**US3292172**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:26:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 2016'	System	16 Aug 2020 02:58:05

US3292172

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:26:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '2016'	System	16 Aug 2020 02:58:05

US3292172

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 2016'	System	16 Aug 2020 02:58:05

US3292172

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '2016'	System	16 Aug 2020 02:58:05

US3292172

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:26:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User closed query 'Per DM CLR: Please review medical diagnosis and confirm if this is a duplicate of medical condition BUNIONECTOMY. If yes, please ensure only one entry is recorded. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 14:35:51
Query 'Per DM CLR: Please review medical diagnosis and confirm if this is a duplicate of medical condition BUNIONECTOMY. If yes, please ensure only one entry is recorded. ' answered with 'removed other' (Site from DM).	Dawn Killian (b) (4)	26 Oct 2020 19:25:39
User opened query 'Per DM CLR: Please review medical diagnosis and confirm if this is a duplicate of medical condition BUNIONECTOMY. If yes, please ensure only one entry is recorded. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 13:48:09
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Bunion operation, LLT: Bunionectomy - version MedDRA\\23.0.	Coder Import (b) (4)	16 Aug 2020 05:08:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Aug 2020 05:08:24
Data point term sent to Coder	System	16 Aug 2020 03:00:08
User entered 'Bunion removal'	(b) (4), (b) (6)	16 Aug 2020 02:59:11

US3292172

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 1982'	(b) (4), (b) (6)	16 Aug 2020 02:59:11



US3292172

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:26:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:59:11

**US3292172**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:26:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 02:59:11

US3292172

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 1982'	(b) (4), (b) (6)	16 Aug 2020 02:59:11

US3292172

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:26:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:59:11

US3292172

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 1982'	System	16 Aug 2020 02:59:11

US3292172

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:26:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '1982'	System	16 Aug 2020 02:59:11

US3292172

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 1982'	System	16 Aug 2020 02:59:11

US3292172

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '1982'	System	16 Aug 2020 02:59:11



US3292172

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:26:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Bunion operation, LLT: Bunionectomy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Aug 2020 03:01:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Aug 2020 03:01:21
Data point term sent to Coder	System	16 Aug 2020 03:00:08
User entered 'Bunionectomy'	(b) (4), (b) (6)	16 Aug 2020 02:59:29

US3292172

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 1982'	(b) (4), (b) (6)	16 Aug 2020 02:59:29

US3292172

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:26:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:59:29

**US3292172**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 16:26:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 02:59:29

US3292172

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 1982'	(b) (4), (b) (6)	16 Aug 2020 02:59:29

US3292172

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:26:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:59:29

US3292172

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 1982'	System	16 Aug 2020 02:59:29

US3292172

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:26:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '1982'	System	16 Aug 2020 02:59:29



US3292172

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 1982'	System	16 Aug 2020 02:59:29

US3292172

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '1982'	System	16 Aug 2020 02:59:29

US3292172

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:26:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User closed query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate including the laterality. Please reconcile with the Con Med eCRF as necessary.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 14:36:11
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual impairment and blindness (excl colour blindness), PT: Visual acuity reduced, LLT: Visual acuity decreased - version MedDRA\23.0.	Coder Import (b) (4)	26 Oct 2020 19:46:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	26 Oct 2020 19:46:28
Data point term sent to Coder	System	26 Oct 2020 19:26:51
Query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate including the laterality. Please reconcile with the Con Med eCRF as necessary.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	26 Oct 2020 19:26:03
Coding entries removed.	Dawn Killian (b) (4)	26 Oct 2020 19:25:58
User entered 'bilateral DECREASED VISUAL ACUITY' reason for change: Data Entry Error	Dawn Killian (b) (4)	26 Oct 2020 19:25:58
User opened query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate including the laterality. Please reconcile with the Con Med eCRF as necessary.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 13:49:05
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual impairment and blindness (excl colour blindness), PT: Visual acuity reduced, LLT: Visual acuity decreased - version MedDRA\23.0.	Coder Import (b) (4)	16 Aug 2020 03:01:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Aug 2020 03:01:21
Data point term sent to Coder	System	16 Aug 2020 03:01:09
User entered 'Decreased visual acuity'	(b) (4), (b) (6)	16 Aug 2020 03:00:28

US3292172

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 1983'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:00:28

US3292172

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:26:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 03:00:28

**US3292172**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 16:26:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:00:28

US3292172

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 03:00:28

US3292172

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:26:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 03:00:28



US3292172

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 1983'	System	16 Aug 2020 03:00:28

US3292172

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:26:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '1983'	System	16 Aug 2020 03:00:28

US3292172

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered empty.	System	16 Aug 2020 03:00:28

US3292172

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered empty.	System	16 Aug 2020 03:00:28

US3292172

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:26:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Intermittent headache - version MedDRA\23.0.	Coder Import (b) (4)	16 Aug 2020 03:01:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Aug 2020 03:01:21
Data point term sent to Coder	System	16 Aug 2020 03:01:08
User entered 'Intermittent headache'	(b) (4), (b) (6)	16 Aug 2020 03:01:05

US3292172

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 1980'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:01:05

US3292172

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:26:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 03:01:05

**US3292172**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 16:26:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 03:01:05



US3292172

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 03:01:05

US3292172

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:26:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 03:01:05

US3292172

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 1980'	System	16 Aug 2020 03:01:05

US3292172

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:26:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '1980'	System	16 Aug 2020 03:01:05

US3292172

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered empty.	System	16 Aug 2020 03:01:05

US3292172

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered empty.	System	16 Aug 2020 03:01:05

US3292172

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:26:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	22 Sep 2020 21:21:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 21:21:44
Data point term sent to Coder	System	22 Sep 2020 21:21:04
User entered 'POST MENOPAUSAL'	Victoria Hernandez (b) (4) (b) (4)	22 Sep 2020 21:20:29

US3292172

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'UN UNK 2019'	(b) (4) Victoria Hernandez (b) (4)	22 Sep 2020 21:20:29



US3292172

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:26:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4) Victoria Hernandez (b) (4)	22 Sep 2020 21:20:29

US3292172

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:26:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User closed query 'Per DM CLR: Please review response to Is the Event/Condition Ongoing? = NO. As this condition's stop date is unexpected, please verify status of this condition and consider updating response to Is the Event/Condition Ongoing, as applicable. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 10:25:47
Query 'Per DM CLR: Please review response to Is the Event/Condition Ongoing? = NO. As this condition's stop date is unexpected, please verify status of this condition and consider updating response to Is the Event/Condition Ongoing, as applicable. ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	20 Oct 2020 19:36:08
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	20 Oct 2020 19:36:04
User opened query 'Per DM CLR: Please review response to Is the Event/Condition Ongoing? = NO. As this condition's stop date is unexpected, please verify status of this condition and consider updating response to Is the Event/Condition Ongoing, as applicable. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 03:15:12
User entered 'No (N)'	Victoria Hernandez (b) (4)	22 Sep 2020 21:20:29

US3292172

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty.	(b) (4) Victoria Hernandez (b) (4)	22 Sep 2020 21:20:29

US3292172

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:26:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Dawn Killian (b) (4)	20 Oct 2020 19:36:04
	(b) (4)	
User entered '1'	Victoria Hernandez (b) (4)	22 Sep 2020 21:20:29
	(b) (4)	

US3292172

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'Jan 2019'	System	22 Sep 2020 21:20:29

US3292172

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:26:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '2019'	System	22 Sep 2020 21:20:29

US3292172

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered empty.	System	22 Sep 2020 21:20:29

US3292172

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered empty.	System	22 Sep 2020 21:20:29



US3292172

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 03:09:18

US3292172

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '13 Aug 2020'	(b) (4), (b) (6)	16 Aug 2020 03:09:18

US3292172

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User closed query 'Per CDM: Response noted; however Time is required. Please refer to CCGs page 23 for more details. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:35:15
Query 'Per CDM: Response noted; however Time is required. Please refer to CCGs page 23 for more details. Thank you.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	22 Sep 2020 18:14:53
User entered '15:17' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	22 Sep 2020 18:14:48
User opened query 'Per CDM: Response noted; however Time is required. Please refer to CCGs page 23 for more details. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 13:17:57
User closed query 'Data is required. Please provide.' (Site from System).		24 Aug 2020 13:17:26
Query 'Data is required. Please provide.' answered with 'Combined visit' (Site from System).		16 Aug 2020 03:09:26
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Aug 2020 03:09:18
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 03:09:18

US3292172

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '13 Aug 2020 15:17'	System	22 Sep 2020 18:14:48
User entered empty.	System	16 Aug 2020 03:09:18

US3292172

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '161.6' cm	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:09:18
DataPoint set to visible.	System	13 Aug 2020 22:51:19

US3292172

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '93.9' kg	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:09:18
DataPoint set to visible.	System	13 Aug 2020 22:51:19

US3292172

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
Amendment Manager: User entered '35.95695'	System	16 Sep 2020 23:56:30
User entered '36.0'	System	16 Aug 2020 03:09:18
DataPoint set to visible.	System	13 Aug 2020 22:51:19

US3292172

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'kg/m2'	System	16 Aug 2020 03:09:18
DataPoint set to visible.	System	13 Aug 2020 22:51:19



US3292172

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Aug 2020 03:09:18

US3292172

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User closed query 'Per CDM RQ: Please remove responses from the data field "Route of measurement and If Other, specify" by leaving them blank as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 07:14:03
Query 'Per CDM RQ: Please remove responses from the data field "Route of measurement and If Other, specify" by leaving them blank as appropriate.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	05 Nov 2020 18:45:38
User entered empty; reason for change Data Entry Error	Dawn Killian (b) (4)	05 Nov 2020 18:45:32
User opened query 'Per CDM RQ: Please remove responses from the data field "Route of measurement and If Other, specify" by leaving them blank as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:20:27
User closed query 'Per CDM: Please remove data as this field should be blank.' (Site from DM).		05 Nov 2020 18:20:27
Query 'Per CDM: Please remove data as this field should be blank.' answered with 'nd' (Site from DM).		07 Oct 2020 17:56:49
User opened query 'Per CDM: Please remove data as this field should be blank.' (Site from DM).		07 Oct 2020 16:37:55
User entered 'Other (Other)'		16 Aug 2020 03:09:18

US3292172

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty; reason for change Data Entry Error	(b) (4)	
	Dawn Killian (b) (4)	05 Nov 2020 18:45:32
User closed query 'Per CDM: Please remove data as this field should be blank.' (Site from DM).	(b) (4)	
Query 'Per CDM: Please remove data as this field should be blank.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:20:50
User opened query 'Per CDM: Please remove data as this field should be blank.' (Site from DM).		07 Oct 2020 17:56:55
User entered missing code ND - Not Done.		07 Oct 2020 16:38:02
		16 Aug 2020 03:09:18

US3292172

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:09:18

US3292172

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'bpm'	System	16 Aug 2020 03:09:18

US3292172

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Aug 2020 03:09:18

US3292172

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'breaths/min'	System	16 Aug 2020 03:09:18

US3292172

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Aug 2020 03:09:18



US3292172

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'mmHg'	System	16 Aug 2020 03:09:18

US3292172

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Aug 2020 03:09:18

US3292172

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'mmHg'	System	16 Aug 2020 03:09:18

US3292172

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56

US3292172

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56

US3292172

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:26:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 03:14:36

US3292172

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:26:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Sep 2020 16:06:29
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		10 Sep 2020 19:20:27
User entered '13 Aug 2020'	(b) (4), (b) (6)	16 Aug 2020 03:14:36

US3292172

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:26:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '13 Aug 2020'	(b) (4), (b) (6)	16 Aug 2020 03:07:29



US3292172

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:26:50

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:07:29

US3292172

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:26:50

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 16:46:56
Query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	22 Sep 2020 21:20:35
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 04:54:02
User entered 'Post-menopausal (POST-MENOPAUSAL)'		16 Aug 2020 03:07:29

US3292172

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:26:50

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:07:29

US3292172

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:26:50

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 03:07:29

US3292172

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:26:50

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:07:29

US3292172

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:26:50

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'un UNK 2019'	(b) (4), (b) (6)	16 Aug 2020 03:07:29

US3292172

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:26:50

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:07:29

US3292172

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:50

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:08:32



US3292172

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:50

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:08:32

US3292172

Folder: Screening

Form: Risk of Exposure

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**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 03:08:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:50

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 03:08:32

US3292172

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:50

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 03:08:32

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Folder: Screening

Form: Risk of Exposure

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 03:08:32

US3292172

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:50

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 03:08:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:50

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 03:08:32

US3292172

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:50

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:08:32



US3292172

Folder: Screening

Form: Risk of Exposure

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**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 03:08:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:50

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:08:32

US3292172

Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 03:08:32

US3292172

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:50

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:08:32

US3292172

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:50

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 03:08:32

US3292172

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:50

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 03:08:32

US3292172

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 03:08:32

US3292172

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:50

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:08:32



US3292172

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:50

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 03:08:32

US3292172

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:50

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'l'	(b) (4), (b) (6)	16 Aug 2020 03:08:32

US3292172

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:50

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 03:08:32

US3292172

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:26:50

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:08:32

US3292172

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:26:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 03:13:07

**US3292172**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:26:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '13 Aug 2020'	(b) (4), (b) (6)	16 Aug 2020 03:13:07

US3292172

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Aug 2020 03:13:07

US3292172

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:26:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'VISIT1'	System	16 Aug 2020 03:13:07



US3292172

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 22:14:20

US3292172

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:26:50

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 04:23:56
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:23:56
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 22:14:20
User entered '104156' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 22:14:20

US3292172

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:26:50

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 22:14:20

US3292172

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:26:50

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 03:14:58

US3292172

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:26:50

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 03:14:58

US3292172

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:26:50

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 03:14:58

**US3292172**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:26:50**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 03:14:58

US3292172

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:26:50

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 03:14:58



US3292172

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:26:50

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:20:31
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:11:38

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:26:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:26:50

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:26:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:26:50

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	8 Mar 2021 01:09:30
User accepted default value 'Pre-Dose (PREDOSE)'		6 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '13 Aug 2020'	(b) (4), (b) (6)	16 Aug 2020 03:11:11



US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '15:17'	(b) (4), (b) (6)	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered '13 Aug 2020 15:17'	System	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '36.9' C	(b) (4), (b) (6)	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '80'	(b) (4), (b) (6)	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'bpm'	System	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '12'	(b) (4), (b) (6)	16 Aug 2020 03:11:11



US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'breaths/min'	System	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '122'	(b) (4), (b) (6)	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'mmHg'	System	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '83'	(b) (4), (b) (6)	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'mmHg'	System	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:26:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:26:50

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User accepted default value 'Post-Dose (POSTDOSE)'		16 Aug 2020 03:11:11



US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '13 Aug 2020'	(b) (4), (b) (6)	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	(b) (4), (b) (6)
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'as per protocol post dose vitals can be completed 30 minutes after dosing' (Site from System).		17 Aug 2020 18:48:34
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		16 Aug 2020 03:11:36
User entered '17:56'	(b) (4), (b) (6)	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered '13 Aug 2020 17:56'	System	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '36.5' C	(b) (4), (b) (6)	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '69'	(b) (4), (b) (6)	16 Aug 2020 03:11:11



US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'bpm'	System	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '12'	(b) (4), (b) (6)	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'breaths/min'	System	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '131'	(b) (4), (b) (6)	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'mmHg'	System	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '89'	(b) (4), (b) (6)	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'mmHg'	System	16 Aug 2020 03:11:11

US3292172

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:26:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	(b) (4) System	16 Aug 2020 03:13:33
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	16 Aug 2020 03:13:18
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 03:13:18



US3292172

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:26:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered empty; reason for change Data Entry Error	(b) (4)	16 Aug 2020 03:13:33
User entered '13 Aug 2020'	(b) (4), (b) (6)	16 Aug 2020 03:13:18

US3292172

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:26:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 22:51:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Nathan Cortez (b) (4)	13 Aug 2020 22:51:44
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 22:51:37
User entered empty.	Nathan Cortez (b) (4)	13 Aug 2020 22:51:37

US3292172

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:26:50

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered empty.	(b) (4) Nathan Cortez (b) (4)	13 Aug 2020 22:51:37

US3292172

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered empty.	(b) (4) Nathan Cortez (b) (4)	13 Aug 2020 22:51:37

US3292172

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:26:50

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 22:51:44
User entered empty.	System	13 Aug 2020 22:51:37

US3292172

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:26:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '13 Aug 2020'	(b) (4) Nathan Cortez (b) (4)	13 Aug 2020 22:51:37

US3292172

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:26:50

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '17:20'	(b) (4) Nathan Cortez (b) (4)	13 Aug 2020 22:51:37

US3292172

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:26:50

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered '13 Aug 2020 17:20'	System	13 Aug 2020 22:51:37



US3292172

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:26:50

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'Left Arm (LEFT ARM)'	(b) (4) Nathan Cortez (b) (4)	13 Aug 2020 22:51:37

US3292172

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:26:50

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'ONCE'	System	13 Aug 2020 22:51:44
User entered empty.	System	13 Aug 2020 22:51:37

US3292172

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:26:50

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 22:51:44
User entered empty.	System	13 Aug 2020 22:51:37

US3292172

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 03:14:01

US3292172

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '13 Aug 2020'	(b) (4), (b) (6)	16 Aug 2020 03:14:01

**US3292172**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:26:50**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '15:26'	(b) (4), (b) (6)	16 Aug 2020 03:14:01

US3292172

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered '13 Aug 2020 15:26'	System	16 Aug 2020 03:14:01

US3292172

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:26:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '13 Aug 2020'	(b) (4), (b) (6)	16 Aug 2020 03:14:18



US3292172

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:26:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	16 Aug 2020 03:14:18

US3292172

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:26:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 03:14:18

US3292172

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:26:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '15:47'	(b) (4), (b) (6)	16 Aug 2020 03:14:18

US3292172

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:26:50

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered '13 Aug 2020 15:47'	System	16 Aug 2020 03:14:18

US3292172

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:26:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	16 Aug 2020 03:14:18

US3292172

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:26:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 03:14:18

**US3292172**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:26:50**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 03:14:18

US3292172

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:26:50

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered empty.	System	16 Aug 2020 03:14:18



US3292172

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:26:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 03:15:04

US3292172

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:26:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'l'	System	16 Aug 2020 03:15:04

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T17:59:56', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '0ada2761-9cfa-4fd9-b82c-c559c3386684' User entered 'Yes (Y)'	System	13 Aug 2020 23:00:20
	System	13 Aug 2020 23:00:20

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T18:00:04', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '0ada2761-9cfa-4fd9-b82c-c559c3386684' User entered '97.3'	System	13 Aug 2020 23:00:20
	System	13 Aug 2020 23:00:20

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T18:00:07', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '0ada2761-9cfa-4fd9-b82c-c559c3386684' User entered 'No (N)'	System	13 Aug 2020 23:00:20
	System	13 Aug 2020 23:00:20

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T18:00:18', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '0ada2761-9cfa-4fd9-b82c-c559c3386684' User entered '13 Aug 2020 18:00'	System	13 Aug 2020 23:00:20
	System	13 Aug 2020 23:00:20

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '13 Aug 2020 17:40'	System	13 Aug 2020 22:51:37



US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '13 Aug 2020 20:10'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T21:06:22', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '6d3ebbd0-b665-4a53-9b5a-4d3bd3c08058' User entered 'Yes (Y)'	System	14 Aug 2020 02:07:35
	System	14 Aug 2020 02:07:35

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T21:07:16', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '6d3ebbd0-b665-4a53-9b5a-4d3bd3c08058' User entered '98.1'	System	14 Aug 2020 02:07:35
	System	14 Aug 2020 02:07:35

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T21:07:26', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '6d3ebbd0-b665-4a53-9b5a-4d3bd3c08058'	System	14 Aug 2020 02:07:35
User entered 'No (N)'	System	14 Aug 2020 02:07:35

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T21:07:34', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '6d3ebbd0-b665-4a53-9b5a-4d3bd3c08058'	System	14 Aug 2020 02:07:35
User entered '13 Aug 2020 21:07'	System	14 Aug 2020 02:07:35

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '13 Aug 2020 21:05'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 22:51:37



US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered 'Day 2'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:26:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-14T22:11:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '8bb5f2e8-678a-4acb-b7c5-acbf19b8ac5b' User entered 'Yes (Y)'	System	15 Aug 2020 03:12:04
	System	15 Aug 2020 03:12:04

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:26:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-14T22:11:53', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '8bb5f2e8-678a-4acb-b7c5-acbf19b8ac5b' User entered '97.9'	System	15 Aug 2020 03:12:04
	System	15 Aug 2020 03:12:04

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-14T22:11:56', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '8bb5f2e8-678a-4acb-b7c5-acbf19b8ac5b' User entered 'No (N)'	System	15 Aug 2020 03:12:04
	System	15 Aug 2020 03:12:04

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-14T22:12:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '8bb5f2e8-678a-4acb-b7c5-acbf19b8ac5b' User entered '14 Aug 2020 22:12'	System	15 Aug 2020 03:12:04
	System	15 Aug 2020 03:12:04

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered 'Day 3'	System	13 Aug 2020 22:51:37



US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:26:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-15T20:30:24', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'c3a151ab-7de3-4af3-8f67-091dff1dd818' User entered 'Yes (Y)'	System	16 Aug 2020 01:30:39
	System	16 Aug 2020 01:30:39

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:26:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-15T20:30:30', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'c3a151ab-7de3-4af3-8f67-091dff1dd818' User entered '97.6'	System	16 Aug 2020 01:30:39
	System	16 Aug 2020 01:30:39

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-15T20:30:33', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'c3a151ab-7de3-4af3-8f67-091dff1dd818'	System	16 Aug 2020 01:30:39
User entered 'No (N)'	System	16 Aug 2020 01:30:39

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-15T20:30:36', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'c3a151ab-7de3-4af3-8f67-091dff1dd818'	System	16 Aug 2020 01:30:39
User entered '15 Aug 2020 20:30'	System	16 Aug 2020 01:30:39

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered 'Day 4'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:26:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-16T21:05:13', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '70e845c6-6a5c-4959-9e64-3091d2aa165d' User entered 'Yes (Y)'	System	17 Aug 2020 02:05:26
	System	17 Aug 2020 02:05:26



US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:26:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-16T21:05:18', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '70e845c6-6a5c-4959-9e64-3091d2aa165d' User entered '97.5'	System	17 Aug 2020 02:05:26
	System	17 Aug 2020 02:05:26

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-16T21:05:21', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '70e845c6-6a5c-4959-9e64-3091d2aa165d' User entered 'No (N)'	System	17 Aug 2020 02:05:26
	System	17 Aug 2020 02:05:26

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-16T21:05:25', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '70e845c6-6a5c-4959-9e64-3091d2aa165d' User entered '16 Aug 2020 21:05'	System	17 Aug 2020 02:05:26
	System	17 Aug 2020 02:05:26

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered 'Day 5'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:26:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-17T20:25:24', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '824a7fc5-ebe6-45c6-9b2c-8dce1d1ef72e' User entered 'Yes (Y)'	System	18 Aug 2020 01:25:38
	System	18 Aug 2020 01:25:38

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:26:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-17T20:25:29', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '824a7fc5-ebe6-45c6-9b2c-8dce1d1ef72e' User entered '97.2'	System	18 Aug 2020 01:25:38
	System	18 Aug 2020 01:25:38



US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-17T20:25:32', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '824a7fc5-ebe6-45c6-9b2c-8dce1d1ef72e'	System	18 Aug 2020 01:25:38
User entered 'No (N)'	System	18 Aug 2020 01:25:38

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-17T20:25:35', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '824a7fc5-ebe6-45c6-9b2c-8dce1d1ef72e' User entered '17 Aug 2020 20:25'	System	18 Aug 2020 01:25:38
	System	18 Aug 2020 01:25:38

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered 'Day 6'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:26:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T04:44:53', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'ff69e3b3-fd71-4962-8fb7-f2979bb8f474' User entered 'Yes (Y)'	System	19 Aug 2020 09:45:15
	System	19 Aug 2020 09:45:15

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:26:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T04:45:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'ff69e3b3-fd71-4962-8fb7-f2979bb8f474' User entered '97.5'	System	19 Aug 2020 09:45:15
	System	19 Aug 2020 09:45:15

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T04:45:09', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'ff69e3b3-fd71-4962-8fb7-f2979bb8f474'	System	19 Aug 2020 09:45:15
User entered 'No (N)'	System	19 Aug 2020 09:45:15



US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T04:45:11', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'ff69e3b3-fd71-4962-8fb7-f2979bb8f474'	System	19 Aug 2020 09:45:15
User entered '19 Aug 2020 04:45'	System	19 Aug 2020 09:45:15

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered 'Day 7'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:26:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T21:31:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '54c591cc-49cf-48ef-8e94-10737ff12ee0' User entered 'Yes (Y)'	System	20 Aug 2020 02:31:14
	System	20 Aug 2020 02:31:14

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:26:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T21:31:05', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '54c591cc-49cf-48ef-8e94-10737ff12ee0' User entered '97.3'	System	20 Aug 2020 02:31:14
	System	20 Aug 2020 02:31:14

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T21:31:09', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '54c591cc-49cf-48ef-8e94-10737ff12ee0'	System	20 Aug 2020 02:31:14
User entered 'No (N)'	System	20 Aug 2020 02:31:14

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T21:31:13', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '54c591cc-49cf-48ef-8e94-10737ff12ee0'	System	20 Aug 2020 02:31:14
User entered '19 Aug 2020 21:31'	System	20 Aug 2020 02:31:14



US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T18:00:28', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '9274902b-838f-4072-8d9e-3a08af6c620f' User entered 'None (1)'	System	13 Aug 2020 23:00:47
	System	13 Aug 2020 23:00:47

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T18:00:32', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '9274902b-838f-4072-8d9e-3a08af6c620f' User entered 'No (N)'	System	13 Aug 2020 23:00:47
	System	13 Aug 2020 23:00:47

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T18:00:35', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '9274902b-838f-4072-8d9e-3a08af6c620f' User entered 'No (N)'	System	13 Aug 2020 23:00:47
	System	13 Aug 2020 23:00:47

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T18:00:39', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '9274902b-838f-4072-8d9e-3a08af6c620f' User entered 'None (1)'	System	13 Aug 2020 23:00:47
	System	13 Aug 2020 23:00:47

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T18:00:42', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '9274902b-838f-4072-8d9e-3a08af6c620f' User entered '13 Aug 2020 18:00'	System	13 Aug 2020 23:00:47
	System	13 Aug 2020 23:00:47



US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '13 Aug 2020 17:40'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '13 Aug 2020 20:10'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T21:07:42', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'f4520dad-e7ad-4c76-b150-aec75fe66f8e'	System	14 Aug 2020 02:08:09
User entered 'None (1)'	System	14 Aug 2020 02:08:09

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T21:07:51', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'f4520dad-e7ad-4c76-b150-aec75fe66f8e' User entered 'No (N)'	System	14 Aug 2020 02:08:09
	System	14 Aug 2020 02:08:09

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T21:07:57', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'f4520dad-e7ad-4c76-b150-aec75fe66f8e' User entered 'No (N)'	System	14 Aug 2020 02:08:09
	System	14 Aug 2020 02:08:09

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T21:08:04', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'f4520dad-e7ad-4c76-b150-aec75fe66f8e' User entered 'None (1)'	System	14 Aug 2020 02:08:09
	System	14 Aug 2020 02:08:09

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T21:08:08', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'f4520dad-e7ad-4c76-b150-aec75fe66f8e' User entered '13 Aug 2020 21:08'	System	14 Aug 2020 02:08:09
	System	14 Aug 2020 02:08:09



US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '13 Aug 2020 21:05'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered 'Day 2'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-14T22:12:10', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'e2d3486a-9474-4a30-8433-22d9815e9dc0'	System	15 Aug 2020 03:12:33
User entered 'None (1)'	System	15 Aug 2020 03:12:33

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:26:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-14T22:12:16', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'e2d3486a-9474-4a30-8433-22d9815e9dc0' User entered 'No (N)'	System	15 Aug 2020 03:12:33
	System	15 Aug 2020 03:12:33

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-14T22:12:21', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'e2d3486a-9474-4a30-8433-22d9815e9dc0' User entered 'No (N)'	System	15 Aug 2020 03:12:33
	System	15 Aug 2020 03:12:33

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-14T22:12:27', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'e2d3486a-9474-4a30-8433-22d9815e9dc0'	System	15 Aug 2020 03:12:33
User entered 'None (1)'	System	15 Aug 2020 03:12:33

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-14T22:12:30', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'e2d3486a-9474-4a30-8433-22d9815e9dc0' User entered '14 Aug 2020 22:12'	System	15 Aug 2020 03:12:33
	System	15 Aug 2020 03:12:33



US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered 'Day 3'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-15T20:30:40', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '597db3c5-d238-4d82-8541-cd61eef2801f' User entered 'None (1)'	System	16 Aug 2020 01:31:01
	System	16 Aug 2020 01:31:01

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:26:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-15T20:30:43', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '597db3c5-d238-4d82-8541-cd61eef2801f' User entered 'No (N)'	System	16 Aug 2020 01:31:01
	System	16 Aug 2020 01:31:01

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-15T20:30:50', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '597db3c5-d238-4d82-8541-cd61eef2801f' User entered 'No (N)'	System	16 Aug 2020 01:31:01
	System	16 Aug 2020 01:31:01

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-15T20:30:52', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '597db3c5-d238-4d82-8541-cd61eef2801f' User entered 'None (1)'	System	16 Aug 2020 01:31:01
	System	16 Aug 2020 01:31:01

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-15T20:30:55', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '597db3c5-d238-4d82-8541-cd61eef2801f' User entered '15 Aug 2020 20:30'	System	16 Aug 2020 01:31:01
	System	16 Aug 2020 01:31:01



US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered 'Day 4'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-16T21:05:29', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'e4e6f3d5-dae2-44fc-ab6a-caf1150ed35d'	System	17 Aug 2020 02:05:47
User entered 'None (1)'	System	17 Aug 2020 02:05:47

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:26:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-16T21:05:32', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'e4e6f3d5-dae2-44fc-ab6a-caf1150ed35d' User entered 'No (N)'	System	17 Aug 2020 02:05:47
	System	17 Aug 2020 02:05:47

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-16T21:05:33', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'e4e6f3d5-dae2-44fc-ab6a-caf1150ed35d' User entered 'No (N)'	System	17 Aug 2020 02:05:47
	System	17 Aug 2020 02:05:47

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-16T21:05:35', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'e4e6f3d5-dae2-44fc-ab6a-caf1150ed35d'	System	17 Aug 2020 02:05:47
User entered 'None (1)'	System	17 Aug 2020 02:05:47

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-16T21:05:45', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'e4e6f3d5-dae2-44fc-ab6a-caf1150ed35d' User entered '16 Aug 2020 21:05'	System	17 Aug 2020 02:05:47
	System	17 Aug 2020 02:05:47



US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered 'Day 5'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-17T20:25:39', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '99809c2d-53a5-4834-a0e7-cda98cec4133'	System	18 Aug 2020 01:25:49
User entered 'None (1)'	System	18 Aug 2020 01:25:49

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:26:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-17T20:25:41', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '99809c2d-53a5-4834-a0e7-cda98cec4133'	System	18 Aug 2020 01:25:49
User entered 'No (N)'	System	18 Aug 2020 01:25:49

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-17T20:25:43', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '99809c2d-53a5-4834-a0e7-cda98cec4133'	System	18 Aug 2020 01:25:49
User entered 'No (N)'	System	18 Aug 2020 01:25:49

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-17T20:25:46', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '99809c2d-53a5-4834-a0e7-cda98cec4133'	System	18 Aug 2020 01:25:49
User entered 'None (1)'	System	18 Aug 2020 01:25:49

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-17T20:25:48', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '99809c2d-53a5-4834-a0e7-cda98cec4133'	System	18 Aug 2020 01:25:49
User entered '17 Aug 2020 20:25'	System	18 Aug 2020 01:25:49



US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered 'Day 6'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T04:45:19', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'd6e35e38-0859-452a-9cd6-f3f433e4716c' User entered 'None (1)'	System	19 Aug 2020 09:45:32
	System	19 Aug 2020 09:45:32

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:26:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T04:45:24', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'd6e35e38-0859-452a-9cd6-f3f433e4716c' User entered 'No (N)'	System	19 Aug 2020 09:45:32
	System	19 Aug 2020 09:45:32

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T04:45:26', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'd6e35e38-0859-452a-9cd6-f3f433e4716c' User entered 'No (N)'	System	19 Aug 2020 09:45:32
	System	19 Aug 2020 09:45:32

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T04:45:28', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'd6e35e38-0859-452a-9cd6-f3f433e4716c' User entered 'None (1)'	System	19 Aug 2020 09:45:32
	System	19 Aug 2020 09:45:32

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T04:45:30', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'd6e35e38-0859-452a-9cd6-f3f433e4716c' User entered '19 Aug 2020 04:45'	System	19 Aug 2020 09:45:32
	System	19 Aug 2020 09:45:32



US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered 'Day 7'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T21:31:17', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'de5cbcea-37dc-455b-921b-202152ced617'	System	20 Aug 2020 02:31:34
User entered 'None (1)'	System	20 Aug 2020 02:31:34

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:26:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T21:31:21', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'de5cbcea-37dc-455b-921b-202152ced617'	System	20 Aug 2020 02:31:34
User entered 'No (N)'	System	20 Aug 2020 02:31:34

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T21:31:24', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'de5cbcea-37dc-455b-921b-202152ced617'	System	20 Aug 2020 02:31:34
User entered 'No (N)'	System	20 Aug 2020 02:31:34

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T21:31:27', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'de5cbcea-37dc-455b-921b-202152ced617'	System	20 Aug 2020 02:31:34
User entered 'None (1)'	System	20 Aug 2020 02:31:34

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T21:31:30', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'de5cbcea-37dc-455b-921b-202152ced617'	System	20 Aug 2020 02:31:34
User entered '19 Aug 2020 21:31'	System	20 Aug 2020 02:31:34



US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T18:00:47', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '10c21d8f-9228-425d-af72-c45efcc52d47' User entered 'None (0)'	System	13 Aug 2020 23:01:08
	System	13 Aug 2020 23:01:08

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T18:00:50', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '10c21d8f-9228-425d-af72-c45efcc52d47'	System	13 Aug 2020 23:01:08
User entered 'None (0)'	System	13 Aug 2020 23:01:08

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T18:00:52', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '10c21d8f-9228-425d-af72-c45efcc52d47' User entered 'None (0)'	System	13 Aug 2020 23:01:08
	System	13 Aug 2020 23:01:08

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T18:00:55', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '10c21d8f-9228-425d-af72-c45efcc52d47' User entered 'None (0)'	System	13 Aug 2020 23:01:08
	System	13 Aug 2020 23:01:08

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T18:00:56', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '10c21d8f-9228-425d-af72-c45efcc52d47' User entered 'None (0)'	System	13 Aug 2020 23:01:08
	System	13 Aug 2020 23:01:08



US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T18:00:58', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '10c21d8f-9228-425d-af72-c45efcc52d47'	System	13 Aug 2020 23:01:08
User entered 'None (0)'	System	13 Aug 2020 23:01:08

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T18:01:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '10c21d8f-9228-425d-af72-c45efcc52d47'	System	13 Aug 2020 23:01:08
User entered 'No (N)'	System	13 Aug 2020 23:01:08

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T18:01:03', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '10c21d8f-9228-425d-af72-c45efcc52d47'	System	13 Aug 2020 23:01:08
User entered '13 Aug 2020 18:01'	System	13 Aug 2020 23:01:08

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '13 Aug 2020 17:40'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '13 Aug 2020 20:10'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T21:08:12', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'b8c422cd-49b0-4302-8d71-d5de48c967da' User entered 'None (0)'	System	14 Aug 2020 02:08:35
	System	14 Aug 2020 02:08:35

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T21:08:16', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'b8c422cd-49b0-4302-8d71-d5de48c967da' User entered 'None (0)'	System	14 Aug 2020 02:08:35
	System	14 Aug 2020 02:08:35



US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T21:08:19', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'b8c422cd-49b0-4302-8d71-d5de48c967da' User entered 'None (0)'	System	14 Aug 2020 02:08:35
	System	14 Aug 2020 02:08:35

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T21:08:21', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'b8c422cd-49b0-4302-8d71-d5de48c967da' User entered 'None (0)'	System	14 Aug 2020 02:08:35
	System	14 Aug 2020 02:08:35

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T21:08:24', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'b8c422cd-49b0-4302-8d71-d5de48c967da' User entered 'None (0)'	System	14 Aug 2020 02:08:35
	System	14 Aug 2020 02:08:35

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T21:08:26', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'b8c422cd-49b0-4302-8d71-d5de48c967da' User entered 'None (0)'	System	14 Aug 2020 02:08:35
	System	14 Aug 2020 02:08:35

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T21:08:29', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'b8c422cd-49b0-4302-8d71-d5de48c967da' User entered 'No (N)'	System	14 Aug 2020 02:08:35
	System	14 Aug 2020 02:08:35

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-13T21:08:32', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'b8c422cd-49b0-4302-8d71-d5de48c967da' User entered '13 Aug 2020 21:08'	System	14 Aug 2020 02:08:35
	System	14 Aug 2020 02:08:35

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '13 Aug 2020 21:05'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 22:51:37



US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered 'Day 2'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:26:50

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-14T22:12:34', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'd56e5b89-e151-4d3e-9a68-89dfc5912961' User entered 'None (0)'	System	15 Aug 2020 03:12:52
	System	15 Aug 2020 03:12:52

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:26:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-14T22:12:36', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'd56e5b89-e151-4d3e-9a68-89dfc5912961'	System	15 Aug 2020 03:12:52
User entered 'None (0)'	System	15 Aug 2020 03:12:52

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:26:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-14T22:12:38', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'd56e5b89-e151-4d3e-9a68-89dfc5912961' User entered 'None (0)'	System	15 Aug 2020 03:12:52
	System	15 Aug 2020 03:12:52

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:26:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-14T22:12:41', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'd56e5b89-e151-4d3e-9a68-89dfc5912961' User entered 'None (0)'	System	15 Aug 2020 03:12:52
	System	15 Aug 2020 03:12:52

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:26:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-14T22:12:43', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'd56e5b89-e151-4d3e-9a68-89dfc5912961' User entered 'None (0)'	System	15 Aug 2020 03:12:52
	System	15 Aug 2020 03:12:52

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:26:50

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-14T22:12:45', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'd56e5b89-e151-4d3e-9a68-89dfc5912961' User entered 'None (0)'	System	15 Aug 2020 03:12:52
	System	15 Aug 2020 03:12:52

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-14T22:12:48', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'd56e5b89-e151-4d3e-9a68-89dfc5912961' User entered 'No (N)'	System	15 Aug 2020 03:12:52
	System	15 Aug 2020 03:12:52



US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:26:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-14T22:12:51', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'd56e5b89-e151-4d3e-9a68-89dfc5912961'	System	15 Aug 2020 03:12:52
User entered '14 Aug 2020 22:12'	System	15 Aug 2020 03:12:52

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered 'Day 3'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:26:50

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-15T20:30:59', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '613c539c-a2c6-464c-8909-2408f07f5464' User entered 'None (0)'	System	16 Aug 2020 01:31:14
	System	16 Aug 2020 01:31:14

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:26:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-15T20:31:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '613c539c-a2c6-464c-8909-2408f07f5464' User entered 'None (0)'	System	16 Aug 2020 01:31:14
	System	16 Aug 2020 01:31:14

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:26:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-15T20:31:02', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '613c539c-a2c6-464c-8909-2408f07f5464' User entered 'None (0)'	System	16 Aug 2020 01:31:14
	System	16 Aug 2020 01:31:14

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:26:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-15T20:31:03', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '613c539c-a2c6-464c-8909-2408f07f5464' User entered 'None (0)'	System	16 Aug 2020 01:31:14
	System	16 Aug 2020 01:31:14



US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:26:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-15T20:31:05', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '613c539c-a2c6-464c-8909-2408f07f5464' User entered 'None (0)'	System	16 Aug 2020 01:31:14
	System	16 Aug 2020 01:31:14

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:26:50

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-15T20:31:06', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '613c539c-a2c6-464c-8909-2408f07f5464' User entered 'None (0)'	System	16 Aug 2020 01:31:14
	System	16 Aug 2020 01:31:14

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-15T20:31:08', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '613c539c-a2c6-464c-8909-2408f07f5464' User entered 'No (N)'	System	16 Aug 2020 01:31:14
	System	16 Aug 2020 01:31:14

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:26:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-15T20:31:11', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '613c539c-a2c6-464c-8909-2408f07f5464' User entered '15 Aug 2020 20:31'	System	16 Aug 2020 01:31:14
	System	16 Aug 2020 01:31:14

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered 'Day 4'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:26:50

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-16T21:05:50', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'e61aef1d-cb51-4b62-9b38-87a0e52648a4' User entered 'None (0)'	System	17 Aug 2020 02:06:08
	System	17 Aug 2020 02:06:08



US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:26:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-16T21:05:52', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'e61aef1d-cb51-4b62-9b38-87a0e52648a4' User entered 'None (0)'	System	17 Aug 2020 02:06:08
	System	17 Aug 2020 02:06:08

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:26:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-16T21:05:56', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'e61aef1d-cb51-4b62-9b38-87a0e52648a4' User entered 'None (0)'	System	17 Aug 2020 02:06:08
	System	17 Aug 2020 02:06:08

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:26:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-16T21:05:57', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'e61aef1d-cb51-4b62-9b38-87a0e52648a4' User entered 'None (0)'	System	17 Aug 2020 02:06:08
	System	17 Aug 2020 02:06:08

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:26:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-16T21:05:59', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'e61aef1d-cb51-4b62-9b38-87a0e52648a4' User entered 'None (0)'	System	17 Aug 2020 02:06:08
	System	17 Aug 2020 02:06:08

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:26:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-16T21:06:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'e61aef1d-eb51-4b62-9b38-87a0e52648a4' User entered 'None (0)'	System	17 Aug 2020 02:06:08
	System	17 Aug 2020 02:06:08

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-16T21:06:03', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'e61aef1d-eb51-4b62-9b38-87a0e52648a4' User entered 'No (N)'	System	17 Aug 2020 02:06:08
	System	17 Aug 2020 02:06:08

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:26:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-16T21:06:05', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'e61aef1d-cb51-4b62-9b38-87a0e52648a4' User entered '16 Aug 2020 21:06'	System	17 Aug 2020 02:06:08
	System	17 Aug 2020 02:06:08

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 22:51:37



US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered 'Day 5'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:26:50

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-17T20:25:51', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '1ce45650-9ebe-4838-8c2c-5a63f23a340e' User entered 'None (0)'	System	18 Aug 2020 01:26:08
	System	18 Aug 2020 01:26:08

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:26:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-17T20:25:53', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '1ce45650-9ebe-4838-8c2c-5a63f23a340e' User entered 'None (0)'	System	18 Aug 2020 01:26:08
	System	18 Aug 2020 01:26:08

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:26:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-17T20:25:56', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '1ce45650-9ebe-4838-8c2c-5a63f23a340e' User entered 'None (0)'	System	18 Aug 2020 01:26:08
	System	18 Aug 2020 01:26:08

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:26:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-17T20:25:58', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '1ce45650-9ebe-4838-8c2c-5a63f23a340e' User entered 'None (0)'	System	18 Aug 2020 01:26:08
	System	18 Aug 2020 01:26:08

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:26:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-17T20:26:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '1ce45650-9ebe-4838-8c2c-5a63f23a340e' User entered 'None (0)'	System	18 Aug 2020 01:26:08
	System	18 Aug 2020 01:26:08

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:26:50

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-17T20:26:01', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '1ce45650-9ebe-4838-8c2c-5a63f23a340e' User entered 'None (0)'	System	18 Aug 2020 01:26:08
	System	18 Aug 2020 01:26:08



US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-17T20:26:03', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '1ce45650-9ebe-4838-8c2c-5a63f23a340e' User entered 'No (N)'	System	18 Aug 2020 01:26:08
	System	18 Aug 2020 01:26:08

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:26:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-17T20:26:05', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '1ce45650-9ebe-4838-8c2c-5a63f23a340e' User entered '17 Aug 2020 20:26'	System	18 Aug 2020 01:26:08
	System	18 Aug 2020 01:26:08

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered 'Day 6'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:26:50

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T04:45:34', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '2dd12b25-2145-4e0d-897e-d530274d1afd' User entered 'None (0)'	System	19 Aug 2020 09:45:53
	System	19 Aug 2020 09:45:53

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:26:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T04:45:36', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '2dd12b25-2145-4e0d-897e-d530274d1afd' User entered 'None (0)'	System	19 Aug 2020 09:45:53
	System	19 Aug 2020 09:45:53

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:26:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T04:45:39', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '2dd12b25-2145-4e0d-897e-d530274d1afd' User entered 'None (0)'	System	19 Aug 2020 09:45:53
	System	19 Aug 2020 09:45:53



US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:26:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T04:45:41', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '2dd12b25-2145-4e0d-897e-d530274d1afd' User entered 'None (0)'	System	19 Aug 2020 09:45:53
	System	19 Aug 2020 09:45:53

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:26:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T04:45:43', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '2dd12b25-2145-4e0d-897e-d530274d1afd' User entered 'None (0)'	System	19 Aug 2020 09:45:53
	System	19 Aug 2020 09:45:53

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:26:50

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T04:45:45', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '2dd12b25-2145-4e0d-897e-d530274d1afd' User entered 'None (0)'	System	19 Aug 2020 09:45:53
	System	19 Aug 2020 09:45:53

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T04:45:48', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '2dd12b25-2145-4e0d-897e-d530274d1afd' User entered 'No (N)'	System	19 Aug 2020 09:45:53
	System	19 Aug 2020 09:45:53

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:26:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T04:45:50', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '2dd12b25-2145-4e0d-897e-d530274d1afd' User entered '19 Aug 2020 04:45'	System	19 Aug 2020 09:45:53
	System	19 Aug 2020 09:45:53

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered 'Day 7'	System	13 Aug 2020 22:51:37



US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:26:50

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T21:31:34', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'c0248889-e8f7-42fa-97bf-8fea35e37f75'	System	20 Aug 2020 02:31:53
User entered 'None (0)'	System	20 Aug 2020 02:31:53

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:26:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T21:31:37', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'c0248889-e8f7-42fa-97bf-8fea35e37f75'	System	20 Aug 2020 02:31:53
User entered 'None (0)'	System	20 Aug 2020 02:31:53

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:26:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T21:31:39', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'c0248889-e8f7-42fa-97bf-8fea35e37f75'	System	20 Aug 2020 02:31:53
User entered 'None (0)'	System	20 Aug 2020 02:31:53

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:26:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T21:31:42', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'c0248889-e8f7-42fa-97bf-8fea35e37f75'	System	20 Aug 2020 02:31:53
User entered 'None (0)'	System	20 Aug 2020 02:31:53

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:26:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T21:31:44', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'c0248889-e8f7-42fa-97bf-8fea35e37f75'	System	20 Aug 2020 02:31:53
User entered 'None (0)'	System	20 Aug 2020 02:31:53

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:26:50

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T21:31:46', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'c0248889-e8f7-42fa-97bf-8fea35e37f75'	System	20 Aug 2020 02:31:53
User entered 'None (0)'	System	20 Aug 2020 02:31:53

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T21:31:49', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'c0248889-e8f7-42fa-97bf-8fea35e37f75'	System	20 Aug 2020 02:31:53
User entered 'No (N)'	System	20 Aug 2020 02:31:53

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:26:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-08-19T21:31:52', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'c0248889-e8f7-42fa-97bf-8fea35e37f75'	System	20 Aug 2020 02:31:53
User entered '19 Aug 2020 21:31'	System	20 Aug 2020 02:31:53



US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 22:51:37

US3292172

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 22:51:37

US3292172

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	23 Aug 2020 18:04:59

US3292172

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '23 Aug 2020'	(b) (4) Kristy Trevino (b) (4)	23 Aug 2020 18:04:59

US3292172

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	23 Aug 2020 18:04:59

US3292172

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty.	(b) (4) Kristy Trevino (b) (4) (b) (4)	23 Aug 2020 18:04:59

US3292172

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	23 Aug 2020 18:05:07

US3292172

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'l'	System	23 Aug 2020 18:05:07



US3292172

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	29 Aug 2020 16:19:26

US3292172

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '28 Aug 2020'	(b) (4) Kristy Trevino (b) (4)	29 Aug 2020 16:19:26

US3292172

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	29 Aug 2020 16:19:26

US3292172

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty.	(b) (4) Kristy Trevino (b) (4) (b) (4)	29 Aug 2020 16:19:26

US3292172

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	29 Aug 2020 16:20:35

US3292172

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'l'	System	29 Aug 2020 16:20:35

US3292172

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	05 Sep 2020 19:14:45

US3292172

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '5 Sep 2020'	(b) (4) Kristy Trevino (b) (4)	05 Sep 2020 19:14:45



US3292172

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	05 Sep 2020 19:14:45

US3292172

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty.	(b) (4) Kristy Trevino (b) (4)	05 Sep 2020 19:14:45

US3292172

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	05 Sep 2020 19:14:50

US3292172

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'l'	System	05 Sep 2020 19:14:50

US3292172

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:26:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	10 Sep 2020 19:20:27

US3292172

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:26:50

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '10 Sep 2020'	(b) (4) Gerardo Pena (b) (4)	10 Sep 2020 19:20:27

US3292172

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'Clinic (Clinic)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	10 Sep 2020 19:20:27

US3292172

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:26:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'VISIT2'	System	10 Sep 2020 19:20:27



US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User accepted default value 'Pre-Dose (PREDOSE)'	Gerardo Pena (b) (4) (b) (4)	10 Sep 2020 19:22:44

US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	10 Sep 2020 19:22:44

US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '10 Sep 2020'	(b) (4) Gerardo Pena (b) (4)	10 Sep 2020 19:22:44

US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '08:15'	(b) (4) Gerardo Pena (b) (4)	10 Sep 2020 19:22:44

US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered '10 Sep 2020 08:15'	System	10 Sep 2020 19:22:44

US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '36.4' C	(b) (4) Gerardo Pena (b) (4)	10 Sep 2020 19:22:44

US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'Oral (Oral)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	10 Sep 2020 19:22:44

US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	10 Sep 2020 19:22:44



US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '80'	(b) (4) Gerardo Pena (b) (4)	10 Sep 2020 19:22:44

US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'bpm'	System	10 Sep 2020 19:22:44

US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '14'	(b) (4) Gerardo Pena (b) (4) (b) (4)	10 Sep 2020 19:22:44

US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'breaths/min'	System	10 Sep 2020 19:22:44

US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '130'	(b) (4) Gerardo Pena (b) (4)	10 Sep 2020 19:22:44

US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'mmHg'	System	10 Sep 2020 19:22:44

US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '94'	(b) (4) Gerardo Pena (b) (4) (b) (4)	10 Sep 2020 19:22:44

US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:26:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'mmHg'	System	10 Sep 2020 19:22:44



US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User accepted default value 'Post-Dose (POSTDOSE)'	Gerardo Pena (b) (4) (b) (4)	10 Sep 2020 19:23:32

US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	10 Sep 2020 19:23:32

US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '10 Sep 2020'	(b) (4) Gerardo Pena (b) (4)	10 Sep 2020 19:23:32

US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '10:04'	(b) (4) Gerardo Pena (b) (4) (b) (4)	10 Sep 2020 19:23:32

US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered '10 Sep 2020 10:04'	System	10 Sep 2020 19:23:32

US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '36.8' C	(b) (4) Gerardo Pena (b) (4)	10 Sep 2020 19:23:32

US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'Oral (Oral)'	(b) (4) Gerardo Pena (b) (4)	10 Sep 2020 19:23:32

US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered empty.	(b) (4) Gerardo Pena (b) (4)	10 Sep 2020 19:23:32



US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '77'	(b) (4) Gerardo Pena (b) (4)	10 Sep 2020 19:23:32

US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'bpm'	System	10 Sep 2020 19:23:32

US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '16'	(b) (4) Gerardo Pena (b) (4) (b) (4)	10 Sep 2020 19:23:32

US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'breaths/min'	System	10 Sep 2020 19:23:32

US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '116'	(b) (4) Gerardo Pena (b) (4)	10 Sep 2020 19:23:32

US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'mmHg'	System	10 Sep 2020 19:23:32

US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '81'	(b) (4) Gerardo Pena (b) (4)	10 Sep 2020 19:23:32

US3292172

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:26:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'mmHg'	System	10 Sep 2020 19:23:32



US3292172

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:26:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	10 Sep 2020 19:24:10

US3292172

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:26:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '10 Sep 2020'	(b) (4) Gerardo Pena (b) (4)	10 Sep 2020 19:24:10

US3292172

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:26:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'Yes (Y)'	(b) (4) Antonio Gutierrez (b) (4)	10 Sep 2020 14:59:45

US3292172

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:26:50

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	10 Sep 2020 14:59:45

US3292172

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	10 Sep 2020 14:59:45

US3292172

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:26:50

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 14:59:45

US3292172

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:26:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '10 Sep 2020'	(b) (4) Antonio Gutierrez (b) (4)	10 Sep 2020 14:59:45

US3292172

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:26:50

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '09:22'	(b) (4) Antonio Gutierrez (b) (4)	10 Sep 2020 14:59:45



US3292172

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:26:50

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered '10 Sep 2020 09:22'	System	10 Sep 2020 14:59:45

US3292172

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:26:50

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'Left Arm (LEFT ARM)'	(b) (4) Antonio Gutierrez (b) (4)	10 Sep 2020 14:59:45

US3292172

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:26:50

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'ONCE'	System	10 Sep 2020 14:59:45

US3292172

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:26:50

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 14:59:45

US3292172

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	10 Sep 2020 19:24:42

US3292172

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '10 Sep 2020'	(b) (4) Gerardo Pena (b) (4)	10 Sep 2020 19:24:42

US3292172

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '09:27'	(b) (4) Gerardo Pena (b) (4)	10 Sep 2020 19:24:42

US3292172

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered '10 Sep 2020 09:27'	System	10 Sep 2020 19:24:42



US3292172

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:26:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '10 Sep 2020'	(b) (4) Gerardo Pena (b) (4)	10 Sep 2020 19:25:04

US3292172

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:26:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Gerardo Pena (b) (4) (b) (4)	10 Sep 2020 19:25:04

US3292172

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:26:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	10 Sep 2020 19:25:04

US3292172

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:26:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '08:37'	(b) (4) Gerardo Pena (b) (4)	10 Sep 2020 19:25:04

US3292172

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:26:50

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered '10 Sep 2020 08:37'	System	10 Sep 2020 19:25:04

US3292172

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:26:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Gerardo Pena (b) (4) (b) (4)	10 Sep 2020 19:25:04

US3292172

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:26:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	10 Sep 2020 19:25:04

US3292172

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:26:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered empty.	(b) (4) Gerardo Pena (b) (4)	10 Sep 2020 19:25:04



US3292172

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:26:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered empty.	System	10 Sep 2020 19:25:04

US3292172

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	10 Sep 2020 19:25:54

US3292172

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'I'	System	10 Sep 2020 19:25:54

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	10 Sep 2020 14:59:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T10:01:01', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '06d67320-dee8-46e8-bcbb-335e693b2ea2' User entered 'Yes (Y)'	System	10 Sep 2020 15:04:38
	System	10 Sep 2020 15:04:38

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T10:04:30', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '06d67320-dee8-46e8-bcbb-335e693b2ea2' User entered '98.2'	System	10 Sep 2020 15:04:38
	System	10 Sep 2020 15:04:38

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T10:04:34', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '06d67320-dee8-46e8-bcbb-335e693b2ea2'	System	10 Sep 2020 15:04:38
User entered 'No (N)'	System	10 Sep 2020 15:04:38

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T10:04:36', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '06d67320-dee8-46e8-bcbb-335e693b2ea2' User entered '10 Sep 2020 10:04'	System	10 Sep 2020 15:04:38
	System	10 Sep 2020 15:04:38



US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '10 Sep 2020 09:42'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '10 Sep 2020 12:12'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	10 Sep 2020 14:59:45
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T21:31:57', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'ad8ea64b-e169-4d27-82f7-e652a11e1494' User entered 'Yes (Y)'	System	11 Sep 2020 02:32:12
	System	11 Sep 2020 02:32:12

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T21:32:03', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'ad8ea64b-e169-4d27-82f7-e652a11e1494' User entered '97.9'	System	11 Sep 2020 02:32:12
	System	11 Sep 2020 02:32:12

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T21:32:06', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'ad8ea64b-e169-4d27-82f7-e652a11e1494' User entered 'No (N)'	System	11 Sep 2020 02:32:12
	System	11 Sep 2020 02:32:12

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T21:32:08', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'ad8ea64b-e169-4d27-82f7-e652a11e1494'	System	11 Sep 2020 02:32:12
User entered '10 Sep 2020 21:32'	System	11 Sep 2020 02:32:12

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '10 Sep 2020 13:07'	System	10 Sep 2020 14:59:45



US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	10 Sep 2020 14:59:45
User entered 'Day 2'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:26:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-11T19:36:48', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '690c79b4-66a0-4d6e-afbf-5ab8f744f258' User entered 'Yes (Y)'	System	12 Sep 2020 00:37:10
	System	12 Sep 2020 00:37:10

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:26:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-11T19:36:53', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '690c79b4-66a0-4d6e-afbf-5ab8f744f258' User entered '99.6'	System	12 Sep 2020 00:37:10
	System	12 Sep 2020 00:37:10

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-11T19:36:56', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '690c79b4-66a0-4d6e-afbf-5ab8f744f258'	System	12 Sep 2020 00:37:10
User entered 'Yes (Y)'	System	12 Sep 2020 00:37:10

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject took Tylenol 500 mg for fever ' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 13:12:56
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-11T19:37:01', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '690c79b4-66a0-4d6e-afbf-5ab8f744f258' User entered '1'	Kristy Trevino (b) (4) (b) (4)	17 Sep 2020 21:38:33
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	12 Sep 2020 00:37:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-11T19:37:01', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '690c79b4-66a0-4d6e-afbf-5ab8f744f258' User entered '1'	System	12 Sep 2020 00:37:10
User entered '1'	System	12 Sep 2020 00:37:10

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:26:50

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-11T19:37:01', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '690c79b4-66a0-4d6e-afbf-5ab8f744f258'	System	12 Sep 2020 00:37:10
User entered '0'	System	12 Sep 2020 00:37:10

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-11T19:37:05', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '690c79b4-66a0-4d6e-afbf-5ab8f744f258'	System	12 Sep 2020 00:37:10
User entered '11 Sep 2020 19:37'	System	12 Sep 2020 00:37:10



US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	10 Sep 2020 14:59:45
User entered 'Day 3'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:26:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-12T23:07:48', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'b699caeb-539b-4a70-9b06-57487273ff32' User entered 'Yes (Y)'	System	13 Sep 2020 04:08:03
	System	13 Sep 2020 04:08:03

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:26:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-12T23:07:53', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'b699caeb-539b-4a70-9b06-57487273ff32' User entered '97.6'	System	13 Sep 2020 04:08:03
	System	13 Sep 2020 04:08:03

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-12T23:07:55', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'b699caeb-539b-4a70-9b06-57487273ff32'	System	13 Sep 2020 04:08:03
User entered 'No (N)'	System	13 Sep 2020 04:08:03

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-12T23:07:58', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'b699caeb-539b-4a70-9b06-57487273ff32'	System	13 Sep 2020 04:08:03
User entered '12 Sep 2020 23:07'	System	13 Sep 2020 04:08:03

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 14:59:45



US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	10 Sep 2020 14:59:45
User entered 'Day 4'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:26:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-13T21:12:48', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '203de568-a24c-48c3-bffb-8cc619ab8819' User entered 'Yes (Y)'	System	14 Sep 2020 02:13:00
	System	14 Sep 2020 02:13:00

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:26:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-13T21:12:54', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '203de568-a24c-48c3-bffb-8cc619ab8819' User entered '97.6'	System	14 Sep 2020 02:13:00
	System	14 Sep 2020 02:13:00

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-13T21:12:56', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '203de568-a24c-48c3-bffb-8cc619ab8819' User entered 'No (N)'	System	14 Sep 2020 02:13:00
	System	14 Sep 2020 02:13:00

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-13T21:12:59', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '203de568-a24c-48c3-bffb-8cc619ab8819' User entered '13 Sep 2020 21:12'	System	14 Sep 2020 02:13:00
	System	14 Sep 2020 02:13:00

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 14:59:45



US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	10 Sep 2020 14:59:45
User entered 'Day 5'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:26:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-15T05:23:09', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '34372f89-3c06-4501-8b05-4380d2262b2c' User entered 'Yes (Y)'	System	15 Sep 2020 10:23:24
	System	15 Sep 2020 10:23:24

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:26:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-15T05:23:14', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '34372f89-3c06-4501-8b05-4380d2262b2c' User entered '97.6'	System	15 Sep 2020 10:23:24
	System	15 Sep 2020 10:23:24

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-15T05:23:17', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '34372f89-3c06-4501-8b05-4380d2262b2c' User entered 'No (N)'	System	15 Sep 2020 10:23:24
	System	15 Sep 2020 10:23:24

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-15T05:23:19', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '34372f89-3c06-4501-8b05-4380d2262b2c' User entered '15 Sep 2020 05:23'	System	15 Sep 2020 10:23:24
	System	15 Sep 2020 10:23:24

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	10 Sep 2020 14:59:45
User entered 'Day 6'	System	10 Sep 2020 14:59:45



US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:26:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-16T06:16:21', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'eadf3481-a60a-4bdf-a0f0-f31874c26807' User entered 'Yes (Y)'	System	16 Sep 2020 11:16:33
	System	16 Sep 2020 11:16:33

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:26:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-16T06:16:27', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'eadf3481-a60a-4bdf-a0f0-f31874c26807' User entered '97.6'	System	16 Sep 2020 11:16:33
	System	16 Sep 2020 11:16:33

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-16T06:16:29', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'eadf3481-a60a-4bdf-a0f0-f31874c26807' User entered 'No (N)'	System	16 Sep 2020 11:16:33
	System	16 Sep 2020 11:16:33

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-16T06:16:31', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'eadf3481-a60a-4bdf-a0f0-f31874c26807' User entered '16 Sep 2020 06:16'	System	16 Sep 2020 11:16:33
	System	16 Sep 2020 11:16:33

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	10 Sep 2020 14:59:45
User entered 'Day 7'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:26:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-17T06:00:11', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '9a7dcc66-1aef-4745-ba39-423566b86fd3'	System	17 Sep 2020 11:00:24
User entered 'Yes (Y)'	System	17 Sep 2020 11:00:24



US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:26:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-17T06:00:16', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '9a7dcc66-1aef-4745-ba39-423566b86fd3' User entered '97.6'	System	17 Sep 2020 11:00:24
	System	17 Sep 2020 11:00:24

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-17T06:00:19', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '9a7dcc66-1aef-4745-ba39-423566b86fd3'	System	17 Sep 2020 11:00:24
User entered 'No (N)'	System	17 Sep 2020 11:00:24

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-17T06:00:21', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '9a7dcc66-1aef-4745-ba39-423566b86fd3'	System	17 Sep 2020 11:00:24
User entered '17 Sep 2020 06:00'	System	17 Sep 2020 11:00:24

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	10 Sep 2020 14:59:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T10:00:19', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '31c0c387-99e3-4121-8df9-c06394228f29'	System	10 Sep 2020 15:00:37
User entered 'None (1)'	System	10 Sep 2020 15:00:37

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T10:00:24', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '31c0c387-99e3-4121-8df9-c06394228f29'	System	10 Sep 2020 15:00:37
User entered 'No (N)'	System	10 Sep 2020 15:00:37



US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T10:00:26', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '31c0c387-99e3-4121-8df9-c06394228f29'	System	10 Sep 2020 15:00:37
User entered 'No (N)'	System	10 Sep 2020 15:00:37

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T10:00:29', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '31c0c387-99e3-4121-8df9-c06394228f29'	System	10 Sep 2020 15:00:37
User entered 'None (1)'	System	10 Sep 2020 15:00:37

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T10:00:32', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '31c0c387-99e3-4121-8df9-c06394228f29' User entered '10 Sep 2020 10:00'	System	10 Sep 2020 15:00:37
	System	10 Sep 2020 15:00:37

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '10 Sep 2020 09:42'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '10 Sep 2020 12:12'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	10 Sep 2020 14:59:45
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T21:30:14', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '7d9363ff-5cb4-4ca9-a8bb-841e04202f3d'	System	11 Sep 2020 02:31:07
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 02:31:07

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T21:30:28', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '7d9363ff-5cb4-4ca9-a8bb-841e04202f3d'	System	11 Sep 2020 02:31:07
User entered 'No (N)'	System	11 Sep 2020 02:31:07



US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T21:30:38', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '7d9363ff-5cb4-4ca9-a8bb-841e04202f3d' User entered 'No (N)'	System	11 Sep 2020 02:31:07
	System	11 Sep 2020 02:31:07

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T21:30:45', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '7d9363ff-5cb4-4ca9-a8bb-841e04202f3d'	System	11 Sep 2020 02:31:07
User entered 'None (1)'	System	11 Sep 2020 02:31:07

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T21:31:01', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '7d9363ff-5cb4-4ca9-a8bb-841e04202f3d' User entered '10 Sep 2020 21:31'	System	11 Sep 2020 02:31:07
	System	11 Sep 2020 02:31:07

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '10 Sep 2020 13:07'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	10 Sep 2020 14:59:45
User entered 'Day 2'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-11T19:37:20', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '59b88531-9fef-4bd0-9a0f-35e7330a7d23'	System	12 Sep 2020 00:37:47
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	12 Sep 2020 00:37:47

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:26:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-11T19:37:33', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '59b88531-9fef-4bd0-9a0f-35e7330a7d23' User entered 'No (N)'	System	12 Sep 2020 00:37:47
	System	12 Sep 2020 00:37:47



US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-11T19:37:38', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '59b88531-9fef-4bd0-9a0f-35e7330a7d23' User entered 'No (N)'	System	12 Sep 2020 00:37:47
	System	12 Sep 2020 00:37:47

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-11T19:37:41', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '59b88531-9fef-4bd0-9a0f-35e7330a7d23' User entered 'None (1)'	System	12 Sep 2020 00:37:47
	System	12 Sep 2020 00:37:47

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-11T19:37:45', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '59b88531-9fef-4bd0-9a0f-35e7330a7d23'	System	12 Sep 2020 00:37:47
User entered '11 Sep 2020 19:37'	System	12 Sep 2020 00:37:47

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	10 Sep 2020 14:59:45
User entered 'Day 3'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-12T23:08:11', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '6e29d9fa-dc23-49a8-98bd-167d6fe2232f' User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 04:08:29
	System	13 Sep 2020 04:08:29

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:26:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-12T23:08:13', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '6e29d9fa-dc23-49a8-98bd-167d6fe2232f' User entered 'No (N)'	System	13 Sep 2020 04:08:29
	System	13 Sep 2020 04:08:29



US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-12T23:08:18', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '6e29d9fa-dc23-49a8-98bd-167d6fe2232f' User entered 'No (N)'	System	13 Sep 2020 04:08:29
	System	13 Sep 2020 04:08:29

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-12T23:08:24', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '6e29d9fa-dc23-49a8-98bd-167d6fe2232f' User entered 'None (1)'	System	13 Sep 2020 04:08:29
	System	13 Sep 2020 04:08:29

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-12T23:08:26', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '6e29d9fa-dc23-49a8-98bd-167d6fe2232f' User entered '12 Sep 2020 23:08'	System	13 Sep 2020 04:08:29
	System	13 Sep 2020 04:08:29

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	10 Sep 2020 14:59:45
User entered 'Day 4'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-13T21:12:28', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'd266b092-94c6-489c-9abc-d73918a94cc3'	System	14 Sep 2020 02:12:44
User entered 'Does not interfere with activity (2)'	System	14 Sep 2020 02:12:44

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:26:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-13T21:12:31', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'd266b092-94c6-489c-9abc-d73918a94cc3' User entered 'No (N)'	System	14 Sep 2020 02:12:44
	System	14 Sep 2020 02:12:44



US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-13T21:12:32', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'd266b092-94c6-489c-9abc-d73918a94cc3' User entered 'No (N)'	System	14 Sep 2020 02:12:44
	System	14 Sep 2020 02:12:44

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-13T21:12:35', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'd266b092-94c6-489c-9abc-d73918a94cc3' User entered 'None (1)'	System	14 Sep 2020 02:12:44
	System	14 Sep 2020 02:12:44

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-13T21:12:41', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'd266b092-94c6-489c-9abc-d73918a94cc3' User entered '13 Sep 2020 21:12'	System	14 Sep 2020 02:12:44
	System	14 Sep 2020 02:12:44

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	10 Sep 2020 14:59:45
User entered 'Day 5'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-15T05:23:23', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '97946542-0e09-4088-a210-447239dc9871'	System	15 Sep 2020 10:23:35
User entered 'None (1)'	System	15 Sep 2020 10:23:35

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:26:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-15T05:23:26', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '97946542-0e09-4088-a210-447239dc9871' User entered 'No (N)'	System	15 Sep 2020 10:23:35
	System	15 Sep 2020 10:23:35



US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-15T05:23:27', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '97946542-0e09-4088-a210-447239dc9871' User entered 'No (N)'	System	15 Sep 2020 10:23:35
	System	15 Sep 2020 10:23:35

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-15T05:23:29', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '97946542-0e09-4088-a210-447239dc9871'	System	15 Sep 2020 10:23:35
User entered 'None (1)'	System	15 Sep 2020 10:23:35

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-15T05:23:32', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '97946542-0e09-4088-a210-447239dc9871' User entered '15 Sep 2020 05:23'	System	15 Sep 2020 10:23:35
	System	15 Sep 2020 10:23:35

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	10 Sep 2020 14:59:45
User entered 'Day 6'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-16T06:16:39', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'aecead95e-fe55-448d-802c-336c5484f198'	System	16 Sep 2020 11:16:49
User entered 'None (1)'	System	16 Sep 2020 11:16:49

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:26:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-16T06:16:41', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'aeead95e-fe55-448d-802c-336c5484f198'	System	16 Sep 2020 11:16:49
User entered 'No (N)'	System	16 Sep 2020 11:16:49



US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-16T06:16:43', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'aeead95e-fe55-448d-802c-336c5484f198'	System	16 Sep 2020 11:16:49
User entered 'No (N)'	System	16 Sep 2020 11:16:49

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-16T06:16:44', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'aeead95e-fe55-448d-802c-336c5484f198'	System	16 Sep 2020 11:16:49
User entered 'None (1)'	System	16 Sep 2020 11:16:49

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-16T06:16:47', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'aeead95e-fe55-448d-802c-336c5484f198'	System	16 Sep 2020 11:16:49
User entered '16 Sep 2020 06:16'	System	16 Sep 2020 11:16:49

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	10 Sep 2020 14:59:45
User entered 'Day 7'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-17T06:00:25', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'e647774c-f2d4-4c4d-ac6c-68f1bd228956'	System	17 Sep 2020 11:00:36
User entered 'None (1)'	System	17 Sep 2020 11:00:36

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:26:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-17T06:00:27', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'e647774c-f2d4-4c4d-ac6c-68f1bd228956' User entered 'No (N)'	System	17 Sep 2020 11:00:36
	System	17 Sep 2020 11:00:36



US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-17T06:00:28', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'e647774c-f2d4-4c4d-ac6c-68f1bd228956' User entered 'No (N)'	System	17 Sep 2020 11:00:36
	System	17 Sep 2020 11:00:36

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:26:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-17T06:00:29', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'e647774c-f2d4-4c4d-ac6c-68f1bd228956'	System	17 Sep 2020 11:00:36
User entered 'None (1)'	System	17 Sep 2020 11:00:36

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:26:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-17T06:00:32', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'e647774c-f2d4-4c4d-ac6c-68f1bd228956' User entered '17 Sep 2020 06:00'	System	17 Sep 2020 11:00:36
	System	17 Sep 2020 11:00:36

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	10 Sep 2020 14:59:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T10:00:36', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '1b5f49e5-3a65-4c1a-9ee1-cce0b41a45c8' User entered 'None (0)'	System	10 Sep 2020 15:00:53
	System	10 Sep 2020 15:00:53

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T10:00:38', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '1b5f49e5-3a65-4c1a-9ee1-cce0b41a45c8' User entered 'None (0)'	System	10 Sep 2020 15:00:53
	System	10 Sep 2020 15:00:53



US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T10:00:40', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '1b5f49e5-3a65-4c1a-9ee1-cce0b41a45c8' User entered 'None (0)'	System	10 Sep 2020 15:00:53
	System	10 Sep 2020 15:00:53

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T10:00:42', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '1b5f49e5-3a65-4c1a-9ee1-cce0b41a45c8' User entered 'None (0)'	System	10 Sep 2020 15:00:53
	System	10 Sep 2020 15:00:53

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T10:00:44', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '1b5f49e5-3a65-4c1a-9ee1-cce0b41a45c8' User entered 'None (0)'	System	10 Sep 2020 15:00:53
	System	10 Sep 2020 15:00:53

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T10:00:46', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '1b5f49e5-3a65-4c1a-9ee1-cce0b41a45c8' User entered 'None (0)'	System	10 Sep 2020 15:00:53
	System	10 Sep 2020 15:00:53

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T10:00:49', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '1b5f49e5-3a65-4c1a-9ee1-cce0b41a45c8' User entered 'No (N)'	System	10 Sep 2020 15:00:53
	System	10 Sep 2020 15:00:53

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T10:00:51', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '1b5f49e5-3a65-4c1a-9ee1-cce0b41a45c8'	System	10 Sep 2020 15:00:53
User entered '10 Sep 2020 10:00'	System	10 Sep 2020 15:00:53

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '10 Sep 2020 09:42'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '10 Sep 2020 12:12'	System	10 Sep 2020 14:59:45



US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	10 Sep 2020 14:59:45
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T21:31:09', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '2daef9ca-8ae3-44e6-b2d4-62b493ef4225'	System	11 Sep 2020 02:31:53
User entered 'No interference with activity (1)'	System	11 Sep 2020 02:31:53

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T21:31:13', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '2daef9ca-8ae3-44e6-b2d4-62b493ef4225'	System	11 Sep 2020 02:31:53
User entered 'No interference with activity (1)'	System	11 Sep 2020 02:31:53

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T21:31:21', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '2daef9ca-8ae3-44e6-b2d4-62b493ef4225'	System	11 Sep 2020 02:31:53
User entered 'Some interference with activity (2)'	System	11 Sep 2020 02:31:53

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T21:31:29', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '2daef9ca-8ae3-44e6-b2d4-62b493ef4225'	System	11 Sep 2020 02:31:53
User entered 'No interference with activity (1)'	System	11 Sep 2020 02:31:53

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T21:31:33', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '2daef9ca-8ae3-44e6-b2d4-62b493ef4225' User entered 'None (0)'	System	11 Sep 2020 02:31:53
	System	11 Sep 2020 02:31:53

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T21:31:37', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '2daef9ca-8ae3-44e6-b2d4-62b493ef4225' User entered 'None (0)'	System	11 Sep 2020 02:31:53
	System	11 Sep 2020 02:31:53

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T21:31:42', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '2daef9ca-8ae3-44e6-b2d4-62b493ef4225'	System	11 Sep 2020 02:31:53
User entered 'No (N)'	System	11 Sep 2020 02:31:53



US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-10T21:31:50', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '2daef9ca-8ae3-44e6-b2d4-62b493ef4225'	System	11 Sep 2020 02:31:53
User entered '10 Sep 2020 21:31'	System	11 Sep 2020 02:31:53

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '10 Sep 2020 13:07'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	10 Sep 2020 14:59:45
User entered 'Day 2'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:26:50

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-11T19:37:51', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'b66dd636-8927-4a3b-8ce6-9e44b5d74364'	System	12 Sep 2020 00:38:19
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	12 Sep 2020 00:38:19

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:26:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-11T19:37:55', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'b66dd636-8927-4a3b-8ce6-9e44b5d74364'	System	12 Sep 2020 00:38:19
User entered 'Some interference with activity (2)'	System	12 Sep 2020 00:38:19

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:26:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-11T19:37:57', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'b66dd636-8927-4a3b-8ce6-9e44b5d74364'	System	12 Sep 2020 00:38:19
User entered 'Some interference with activity (2)'	System	12 Sep 2020 00:38:19

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:26:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-11T19:38:01', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'b66dd636-8927-4a3b-8ce6-9e44b5d74364'	System	12 Sep 2020 00:38:19
User entered 'Some interference with activity (2)'	System	12 Sep 2020 00:38:19



US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:26:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-11T19:38:04', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'b66dd636-8927-4a3b-8ce6-9e44b5d74364'	System	12 Sep 2020 00:38:19
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	12 Sep 2020 00:38:19

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:26:50

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-11T19:38:10', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'b66dd636-8927-4a3b-8ce6-9e44b5d74364'	System	12 Sep 2020 00:38:19
User entered 'Some interference with activity not requiring medical attention (2)'	System	12 Sep 2020 00:38:19

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-11T19:38:14', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'b66dd636-8927-4a3b-8ce6-9e44b5d74364' User entered 'No (N)'	System	12 Sep 2020 00:38:19
	System	12 Sep 2020 00:38:19

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:26:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-11T19:38:16', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'b66dd636-8927-4a3b-8ce6-9e44b5d74364' User entered '11 Sep 2020 19:38'	System	12 Sep 2020 00:38:19
	System	12 Sep 2020 00:38:19

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	10 Sep 2020 14:59:45
User entered 'Day 3'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:26:50

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-12T23:08:32', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '8aad8e17-c1a0-4d6e-a27f-06c59fe5c6b0'	System	13 Sep 2020 04:08:54
User entered 'No interference with activity (1)'	System	13 Sep 2020 04:08:54



US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:26:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-12T23:08:37', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '8aad8e17-c1a0-4d6e-a27f-06c59fe5c6b0' User entered 'None (0)'	System	13 Sep 2020 04:08:54
	System	13 Sep 2020 04:08:54

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:26:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-12T23:08:39', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '8aad8e17-c1a0-4d6e-a27f-06c59fe5c6b0' User entered 'None (0)'	System	13 Sep 2020 04:08:54
	System	13 Sep 2020 04:08:54

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:26:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-12T23:08:41', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '8aad8e17-c1a0-4d6e-a27f-06c59fe5c6b0' User entered 'None (0)'	System	13 Sep 2020 04:08:54
	System	13 Sep 2020 04:08:54

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:26:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-12T23:08:43', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '8aad8e17-c1a0-4d6e-a27f-06c59fe5c6b0' User entered 'None (0)'	System	13 Sep 2020 04:08:54
	System	13 Sep 2020 04:08:54

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:26:50

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-12T23:08:46', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '8aad8e17-c1a0-4d6e-a27f-06c59fe5c6b0' User entered 'None (0)'	System	13 Sep 2020 04:08:54
	System	13 Sep 2020 04:08:54

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-12T23:08:49', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '8aad8e17-c1a0-4d6e-a27f-06c59fe5c6b0' User entered 'No (N)'	System	13 Sep 2020 04:08:54
	System	13 Sep 2020 04:08:54

**US3292172**

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

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

**Generated On: 09 Jun 2021 16:26:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-12T23:08:51', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '8aad8e17-c1a0-4d6e-a27f-06c59fe5c6b0' User entered '12 Sep 2020 23:08'	System	13 Sep 2020 04:08:54
	System	13 Sep 2020 04:08:54

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 14:59:45



US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	10 Sep 2020 14:59:45
User entered 'Day 4'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:26:50

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-13T21:13:03', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '3e7b9e51-e9b0-45f0-8629-d9838a3cb74a' User entered 'None (0)'	System	14 Sep 2020 02:13:22
	System	14 Sep 2020 02:13:22

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:26:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-13T21:13:05', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '3e7b9e51-e9b0-45f0-8629-d9838a3cb74a' User entered 'None (0)'	System	14 Sep 2020 02:13:22
	System	14 Sep 2020 02:13:22

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:26:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-13T21:13:08', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '3e7b9e51-e9b0-45f0-8629-d9838a3cb74a' User entered 'None (0)'	System	14 Sep 2020 02:13:22
	System	14 Sep 2020 02:13:22

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:26:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-13T21:13:10', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '3e7b9e51-e9b0-45f0-8629-d9838a3cb74a' User entered 'None (0)'	System	14 Sep 2020 02:13:22
	System	14 Sep 2020 02:13:22

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:26:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-13T21:13:12', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '3e7b9e51-e9b0-45f0-8629-d9838a3cb74a' User entered 'None (0)'	System	14 Sep 2020 02:13:22
	System	14 Sep 2020 02:13:22

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:26:50

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-13T21:13:13', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '3e7b9e51-e9b0-45f0-8629-d9838a3cb74a' User entered 'None (0)'	System	14 Sep 2020 02:13:22
	System	14 Sep 2020 02:13:22



US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-13T21:13:16', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '3e7b9e51-e9b0-45f0-8629-d9838a3cb74a' User entered 'No (N)'	System	14 Sep 2020 02:13:22
	System	14 Sep 2020 02:13:22

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:26:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-13T21:13:18', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '3e7b9e51-e9b0-45f0-8629-d9838a3cb74a' User entered '13 Sep 2020 21:13'	System	14 Sep 2020 02:13:22
	System	14 Sep 2020 02:13:22

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	10 Sep 2020 14:59:45
User entered 'Day 5'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:26:50

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-15T05:23:36', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'b85f81fa-7a6b-401f-8e19-98315591039c' User entered 'None (0)'	System	15 Sep 2020 10:23:51
	System	15 Sep 2020 10:23:51

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:26:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-15T05:23:37', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'b85f81fa-7a6b-401f-8e19-98315591039c' User entered 'None (0)'	System	15 Sep 2020 10:23:51
	System	15 Sep 2020 10:23:51

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:26:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-15T05:23:38', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'b85f81fa-7a6b-401f-8e19-98315591039c' User entered 'None (0)'	System	15 Sep 2020 10:23:51
	System	15 Sep 2020 10:23:51



US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:26:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-15T05:23:39', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'b85f81fa-7a6b-401f-8e19-98315591039c' User entered 'None (0)'	System	15 Sep 2020 10:23:51
	System	15 Sep 2020 10:23:51

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:26:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-15T05:23:41', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'b85f81fa-7a6b-401f-8e19-98315591039c' User entered 'None (0)'	System	15 Sep 2020 10:23:51
	System	15 Sep 2020 10:23:51

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:26:50

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-15T05:23:42', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'b85f81fa-7a6b-401f-8e19-98315591039c' User entered 'None (0)'	System	15 Sep 2020 10:23:51
	System	15 Sep 2020 10:23:51

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-15T05:23:45', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'b85f81fa-7a6b-401f-8e19-98315591039c' User entered 'No (N)'	System	15 Sep 2020 10:23:51
	System	15 Sep 2020 10:23:51

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:26:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-15T05:23:49', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'b85f81fa-7a6b-401f-8e19-98315591039c' User entered '15 Sep 2020 05:23'	System	15 Sep 2020 10:23:51
	System	15 Sep 2020 10:23:51

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	10 Sep 2020 14:59:45
User entered 'Day 6'	System	10 Sep 2020 14:59:45



US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:26:50

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-16T06:16:51', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'bf499ee4-eccb-4335-872a-a399da7fdc47' User entered 'None (0)'	System	16 Sep 2020 11:17:08
	System	16 Sep 2020 11:17:08

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:26:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-16T06:16:53', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'bf499ee4-eccb-4335-872a-a399da7fdc47' User entered 'None (0)'	System	16 Sep 2020 11:17:08
	System	16 Sep 2020 11:17:08

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:26:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-16T06:16:56', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'bf499ee4-eccb-4335-872a-a399da7fdc47' User entered 'None (0)'	System	16 Sep 2020 11:17:08
	System	16 Sep 2020 11:17:08

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:26:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-16T06:16:58', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'bf499ee4-eccb-4335-872a-a399da7fdc47' User entered 'None (0)'	System	16 Sep 2020 11:17:08
	System	16 Sep 2020 11:17:08

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:26:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-16T06:17:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'bf499ee4-eccb-4335-872a-a399da7fdc47' User entered 'None (0)'	System	16 Sep 2020 11:17:08
	System	16 Sep 2020 11:17:08

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:26:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-16T06:17:01', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'bf499ee4-eccb-4335-872a-a399da7fdc47' User entered 'None (0)'	System	16 Sep 2020 11:17:08
	System	16 Sep 2020 11:17:08

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-16T06:17:04', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'bf499ee4-eccb-4335-872a-a399da7fdc47'	System	16 Sep 2020 11:17:08
User entered 'No (N)'	System	16 Sep 2020 11:17:08

**US3292172**

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

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

**Generated On: 09 Jun 2021 16:26:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-16T06:17:06', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'bf499ee4-eccb-4335-872a-a399da7fdc47' User entered '16 Sep 2020 06:17'	System	16 Sep 2020 11:17:08
	System	16 Sep 2020 11:17:08



US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	10 Sep 2020 14:59:45
User entered 'Day 7'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:26:50

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-17T06:00:36', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '593dd60d-9392-4bdc-b2ed-dd57e7702ffb' User entered 'None (0)'	System	17 Sep 2020 11:00:50
	System	17 Sep 2020 11:00:50

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:26:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-17T06:00:38', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '593dd60d-9392-4bdc-b2ed-dd57e7702ffb' User entered 'None (0)'	System	17 Sep 2020 11:00:50
	System	17 Sep 2020 11:00:50

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:26:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-17T06:00:40', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '593dd60d-9392-4bdc-b2ed-dd57e7702ffb' User entered 'None (0)'	System	17 Sep 2020 11:00:50
	System	17 Sep 2020 11:00:50

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:26:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-17T06:00:41', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '593dd60d-9392-4bdc-b2ed-dd57e7702ffb' User entered 'None (0)'	System	17 Sep 2020 11:00:50
	System	17 Sep 2020 11:00:50

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:26:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-17T06:00:43', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '593dd60d-9392-4bdc-b2ed-dd57e7702ffb' User entered 'None (0)'	System	17 Sep 2020 11:00:50
	System	17 Sep 2020 11:00:50



US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:26:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-17T06:00:45', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '593dd60d-9392-4bdc-b2ed-dd57e7702ffb' User entered 'None (0)'	System	17 Sep 2020 11:00:50
	System	17 Sep 2020 11:00:50

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-17T06:00:47', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '593dd60d-9392-4bdc-b2ed-dd57e7702ffb' User entered 'No (N)'	System	17 Sep 2020 11:00:50
	System	17 Sep 2020 11:00:50

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:26:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-09-17T06:00:48', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '593dd60d-9392-4bdc-b2ed-dd57e7702ffb' User entered '17 Sep 2020 06:00'	System	17 Sep 2020 11:00:50
	System	17 Sep 2020 11:00:50

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:26:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 14:59:45

US3292172

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:26:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 14:59:45

US3292172

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	17 Sep 2020 21:38:45

US3292172

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '17 Sep 2020'	(b) (4) Kristy Trevino (b) (4)	17 Sep 2020 21:38:45

US3292172

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	17 Sep 2020 21:38:45



US3292172

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty.	(b) (4) Kristy Trevino (b) (4) (b) (4)	17 Sep 2020 21:38:45

US3292172

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	17 Sep 2020 21:39:16

US3292172

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'l'	System	17 Sep 2020 21:39:16

US3292172

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	24 Sep 2020 22:01:33

US3292172

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '24 Sep 2020'	(b) (4) Kristy Trevino (b) (4)	24 Sep 2020 22:01:33

US3292172

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	24 Sep 2020 22:01:33

US3292172

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty.	(b) (4) Kristy Trevino (b) (4) (b) (4)	24 Sep 2020 22:01:33

US3292172

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	24 Sep 2020 22:01:39



US3292172

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'l'	System	24 Sep 2020 22:01:39

US3292172

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 21:01:06

US3292172

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '2 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 21:01:06

US3292172

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Oct 2020 21:01:06

US3292172

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 21:01:06

US3292172

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 21:01:17

US3292172

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'l'	System	02 Oct 2020 21:01:17

US3292172

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:26:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'Yes (Y)'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:53:52



US3292172

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '8 Oct 2020'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:53:52

US3292172

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'Clinic (Clinic)'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:53:52

US3292172

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:26:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'VISIT3'	System	08 Oct 2020 13:53:52

US3292172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'Yes (Y)'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:54:31

US3292172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '8 Oct 2020'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:54:31

US3292172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '07:57'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:54:31

US3292172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered '8 Oct 2020 07:57'	System	08 Oct 2020 13:54:31

US3292172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '36.9' C	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:54:31



US3292172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'Oral (Oral)'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:54:31

US3292172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered empty.	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:54:31

US3292172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '67'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:54:31

US3292172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'bpm'	System	08 Oct 2020 13:54:31

US3292172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '12'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:54:31

US3292172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'breaths/min'	System	08 Oct 2020 13:54:31

US3292172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '118'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:54:31

US3292172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'mmHg'	System	08 Oct 2020 13:54:31



US3292172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '84'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:54:31

US3292172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'mmHg'	System	08 Oct 2020 13:54:31

US3292172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30

US3292172

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30

US3292172

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:26:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'No (N)'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:55:16

US3292172

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:26:50

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered empty.	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:55:16

US3292172

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'Yes (Y)'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:55:35

US3292172

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '8 Oct 2020'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:55:35



US3292172

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered '08:10'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:55:35

US3292172

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered '8 Oct 2020 08:10'	System	08 Oct 2020 13:55:35

US3292172

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:46
User entered 'Yes (Y)'	(b) (4) Kevin Martinez (b) (4)	08 Oct 2020 13:53:44

US3292172

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'I'	System	08 Oct 2020 13:53:44

US3292172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered 'Day 64'	System	13 Aug 2020 22:51:37

US3292172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-10-14T08:41:15', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '03fc7feb-1e9a-445d-8295-bfb4e1536395'	System	14 Oct 2020 13:41:24
User entered 'No (N)'	System	14 Oct 2020 13:41:24

US3292172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-10-14T08:41:18', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '03fc7feb-1e9a-445d-8295-bfb4e1536395'	System	14 Oct 2020 13:41:24
User entered 'No (N)'	System	14 Oct 2020 13:41:24

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-10-14T08:41:21', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '03fc7feb-1e9a-445d-8295-bfb4e1536395'	System	14 Oct 2020 13:41:24
User entered '14 Oct 2020 08:41:21'	System	14 Oct 2020 13:41:24



US3292172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered '13 Oct 2020 00:01'	System	13 Aug 2020 22:51:37

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered '17 Oct 2020 23:59'	System	13 Aug 2020 22:51:37

US3292172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered 'Day 71'	System	13 Aug 2020 22:51:37

US3292172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-10-21T21:04:46', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '9e976338-4ae2-4b53-acd2-56f753b7478e' User entered 'No (N)'	System	22 Oct 2020 02:04:55
	System	22 Oct 2020 02:04:55

US3292172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-10-21T21:04:49', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '9e976338-4ae2-4b53-acd2-56f753b7478e'	System	22 Oct 2020 02:04:55
User entered 'No (N)'	System	22 Oct 2020 02:04:55

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-10-21T21:04:52', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '9e976338-4ae2-4b53-acd2-56f753b7478e' User entered '21 Oct 2020 21:04:52'	System	22 Oct 2020 02:04:55
	System	22 Oct 2020 02:04:55

US3292172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered '20 Oct 2020 00:01'	System	13 Aug 2020 22:51:37

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered '24 Oct 2020 23:59'	System	13 Aug 2020 22:51:37



US3292172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered 'Day 78'	System	13 Aug 2020 22:51:37

US3292172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-10-29T12:00:26', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '485c06e6-3fe6-44d7-8885-7ed05afc6f6e'	System	29 Oct 2020 17:01:15
User entered 'No (N)'	System	29 Oct 2020 17:01:15

US3292172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-10-29T12:00:35', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '485c06e6-3fe6-44d7-8885-7ed05afc6f6e'	System	29 Oct 2020 17:01:15
User entered 'No (N)'	System	29 Oct 2020 17:01:15

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-10-29T12:00:38', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '485c06e6-3fe6-44d7-8885-7ed05afc6f6e' User entered '29 Oct 2020 12:00:38'	System	29 Oct 2020 17:01:15
	System	29 Oct 2020 17:01:15

US3292172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered '27 Oct 2020 00:01'	System	13 Aug 2020 22:51:37

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered '31 Oct 2020 23:59'	System	13 Aug 2020 22:51:37

US3292172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered 'Day 92'	System	13 Aug 2020 22:51:37

US3292172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-11-10T20:23:18', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '206e0378-8772-4562-8d54-b38ac7f77f9b'	System	11 Nov 2020 02:23:59
User entered 'No (N)'	System	11 Nov 2020 02:23:59



US3292172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-11-10T20:23:44', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '206e0378-8772-4562-8d54-b38ac7f77f9b'	System	11 Nov 2020 02:23:59
User entered 'Yes (Y)'	System	11 Nov 2020 02:23:59

US3292172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-11-10T20:23:46', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '206e0378-8772-4562-8d54-b38ac7f77f9b'	System	11 Nov 2020 02:23:59
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Nov 2020 02:23:59

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-11-10T20:23:50', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '206e0378-8772-4562-8d54-b38ac7f77f9b' User entered '10 Nov 2020 20:23:50'	System	11 Nov 2020 02:23:59
	System	11 Nov 2020 02:23:59

US3292172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered '10 Nov 2020 00:01'	System	13 Aug 2020 22:51:37

**US3292172**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
Data entry locked.	System	13 Aug 2020 22:51:37
User entered '14 Nov 2020 23:59'	System	13 Aug 2020 22:51:37

US3292172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	20 Nov 2020 17:56:14
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:56:02
Data entry locked.	System	13 Aug 2020 22:51:37
User entered 'Day 99'	System	13 Aug 2020 22:51:37

US3292172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-11-21T10:10:25', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'f412b473-03c6-4ad6-a499-1045550ab42c'	System	21 Nov 2020 16:10:36
User entered 'No (N)'	System	21 Nov 2020 16:10:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	20 Nov 2020 17:56:14
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:56:02

US3292172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-11-21T10:10:29', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'f412b473-03c6-4ad6-a499-1045550ab42c'	System	21 Nov 2020 16:10:36
User entered 'No (N)'	System	21 Nov 2020 16:10:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	20 Nov 2020 17:56:14
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:56:02



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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-11-21T10:10:33', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'f412b473-03c6-4ad6-a499-1045550ab42c' User entered '21 Nov 2020 10:10:33'	System	21 Nov 2020 16:10:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	20 Nov 2020 17:56:14
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:56:02

US3292172

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
DataPoint activated with code reason code Data required.		20 Nov 2020 17:56:14
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:56:02
Data entry locked.	System	13 Aug 2020 22:51:37
User entered '17 Nov 2020 00:01'	System	13 Aug 2020 22:51:37

**US3292172**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:06
DataPoint activated with code reason code Data required.		20 Nov 2020 17:56:14
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:56:02
Data entry locked.	System	13 Aug 2020 22:51:37
User entered '21 Nov 2020 23:59'	System	13 Aug 2020 22:51:37

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-11-21T10:08:44', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'a5eba233-104a-4b0d-9019-433c42f31767'	System	21 Nov 2020 16:09:00
User entered 'No (N)'	System	21 Nov 2020 16:09:00

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-11-21T10:08:51', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'a5eba233-104a-4b0d-9019-433c42f31767' User entered 'No (N)'	System	21 Nov 2020 16:09:00
	System	21 Nov 2020 16:09:00

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-11-21T10:08:54', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'a5eba233-104a-4b0d-9019-433c42f31767' User entered '21 Nov 2020 10:08:54'	System	21 Nov 2020 16:09:00
	System	21 Nov 2020 16:09:00

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 06:56:02



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-11-28T11:25:38', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '3761ba44-f0c2-499e-945e-b792bc6a8f6b' User entered 'Yes (Y)'	System	28 Nov 2020 17:26:39
	System	28 Nov 2020 17:26:39

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-11-28T11:25:52', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '3761ba44-f0c2-499e-945e-b792bc6a8f6b' User entered 'No (N)'	System	28 Nov 2020 17:26:39

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-11-28T11:25:57', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '3761ba44-f0c2-499e-945e-b792bc6a8f6b' User entered 'No (N)'	System	28 Nov 2020 17:26:39

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-11-28T11:26:17', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '3761ba44-f0c2-499e-945e-b792bc6a8f6b' User entered 'No (N)'	System	28 Nov 2020 17:26:39

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:26:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-11-28T11:26:35', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '3761ba44-f0c2-499e-945e-b792bc6a8f6b' User entered '28 Nov 2020 11:26:35'	System	28 Nov 2020 17:26:39

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-12-05T11:37:56', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'a1501103-a00e-4714-a5f0-1d8be8ed68e0' User entered 'No (N)'	System	05 Dec 2020 17:38:19
	System	05 Dec 2020 17:38:19

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-12-05T11:38:12', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'a1501103-a00e-4714-a5f0-1d8be8ed68e0' User entered 'No (N)'	System	05 Dec 2020 17:38:19

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-12-05T11:38:15', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'a1501103-a00e-4714-a5f0-1d8be8ed68e0' User entered '05 Dec 2020 11:38:15'	System	05 Dec 2020 17:38:19

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-12-13T07:01:03', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '8a81cd59-08aa-4e79-8cf7-1f62222e8285'	System	13 Dec 2020 13:01:19
User entered 'No (N)'	System	13 Dec 2020 13:01:19

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-12-13T07:01:10', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '8a81cd59-08aa-4e79-8cf7-1f62222e8285'	System	13 Dec 2020 13:01:19
User entered 'No (N)'	System	13 Dec 2020 13:01:19

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-12-13T07:01:16', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '8a81cd59-08aa-4e79-8cf7-1f62222e8285' User entered '13 Dec 2020 07:01:16'	System	13 Dec 2020 13:01:19
	System	13 Dec 2020 13:01:19

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-12-19T05:08:28', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '61437d42-3fc7-4909-833b-f6e3abbe8f91' User entered 'No (N)'	System	19 Dec 2020 11:08:37

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-12-19T05:08:32', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '61437d42-3fc7-4909-833b-f6e3abbe8f91' User entered 'No (N)'	System	19 Dec 2020 11:08:37
	System	19 Dec 2020 11:08:37



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-12-19T05:08:35', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '61437d42-3fc7-4909-833b-f6e3abbe8f91' User entered '19 Dec 2020 05:08:35'	System	19 Dec 2020 11:08:37
	System	19 Dec 2020 11:08:37

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-12-27T07:25:51', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '0ff238c8-620b-4e07-81f0-29088efd1a23'	System	27 Dec 2020 13:26:00
User entered 'No (N)'	System	27 Dec 2020 13:26:00

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-12-27T07:25:54', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '0ff238c8-620b-4e07-81f0-29088efd1a23'	System	27 Dec 2020 13:26:00
User entered 'No (N)'	System	27 Dec 2020 13:26:00

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2020-12-27T07:25:57', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '0ff238c8-620b-4e07-81f0-29088efd1a23' User entered '27 Dec 2020 07:25:57'	System	27 Dec 2020 13:26:00
	System	27 Dec 2020 13:26:00

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-01-04T12:01:04', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'c40bb04d-68fa-4115-8df7-a46e4d41d277'	System	04 Jan 2021 18:01:17
User entered 'No (N)'	System	04 Jan 2021 18:01:17

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-01-04T12:01:07', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'c40bb04d-68fa-4115-8df7-a46e4d41d277'	System	04 Jan 2021 18:01:17
User entered 'No (N)'	System	04 Jan 2021 18:01:17

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-01-04T12:01:10', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'c40bb04d-68fa-4115-8df7-a46e4d41d277'	System	04 Jan 2021 18:01:17
User entered '04 Jan 2021 12:01:10'	System	04 Jan 2021 18:01:17

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-01-11T12:00:39', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '7016716f-a94c-48d1-b604-bc36d0b29951' User entered 'No (N)'	System	11 Jan 2021 18:01:08
	System	11 Jan 2021 18:01:08

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-01-11T12:00:42', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '7016716f-a94c-48d1-b604-bc36d0b29951'	System	11 Jan 2021 18:01:08
User entered 'No (N)'	System	11 Jan 2021 18:01:08

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-01-11T12:00:45', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '7016716f-a94c-48d1-b604-bc36d0b29951' User entered '11 Jan 2021 12:00:45'	System	11 Jan 2021 18:01:08

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 06:56:02

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-01-18T12:02:13', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '0e4ad4a1-910b-4b23-8e1c-b508f673ed67' User entered 'No (N)'	System	18 Jan 2021 18:03:04

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-01-18T12:02:17', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '0e4ad4a1-910b-4b23-8e1c-b508f673ed67' User entered 'Yes (Y)'	System	18 Jan 2021 18:03:04
	System	18 Jan 2021 18:03:04



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-01-18T12:02:22', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '0e4ad4a1-910b-4b23-8e1c-b508f673ed67'	System	18 Jan 2021 18:03:04
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Jan 2021 18:03:04

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-01-18T12:02:53', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '0e4ad4a1-910b-4b23-8e1c-b508f673ed67' User entered '18 Jan 2021 12:02:53'	System	18 Jan 2021 18:03:04

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-01-23T13:39:21', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'e8c98989-cc29-4d35-9b5a-06e6b12f9397'	System	23 Jan 2021 19:39:29
User entered 'No (N)'	System	23 Jan 2021 19:39:29

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-01-23T13:39:24', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'e8c98989-cc29-4d35-9b5a-06e6b12f9397'	System	23 Jan 2021 19:39:29
User entered 'No (N)'	System	23 Jan 2021 19:39:29

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-01-23T13:39:27', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'e8c98989-cc29-4d35-9b5a-06e6b12f9397' User entered '23 Jan 2021 13:39:27'	System	23 Jan 2021 19:39:29
	System	23 Jan 2021 19:39:29



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-02-01T12:00:58', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '4c79414b-3599-4f02-9bf1-8244df977fbc' User entered 'No (N)'	System	01 Feb 2021 18:02:31
	System	01 Feb 2021 18:02:31

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-02-01T12:01:03', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '4c79414b-3599-4f02-9bf1-8244df977fbc'	System	01 Feb 2021 18:02:31
User entered 'No (N)'	System	01 Feb 2021 18:02:31

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-02-01T12:01:06', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '4c79414b-3599-4f02-9bf1-8244df977fbc' User entered '01 Feb 2021 12:01:06'	System	01 Feb 2021 18:02:31
	System	01 Feb 2021 18:02:31

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-02-06T10:23:16', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '29651ea3-ce5c-428e-aa04-6675f44fa56b' User entered 'No (N)'	System	06 Feb 2021 16:23:49

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-02-06T10:23:30', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '29651ea3-ce5c-428e-aa04-6675f44fa56b'	System	06 Feb 2021 16:23:49
User entered 'Yes (Y)'	System	06 Feb 2021 16:23:49

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-02-06T10:23:34', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '29651ea3-ce5c-428e-aa04-6675f44fa56b'	System	06 Feb 2021 16:23:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Feb 2021 16:23:49

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-02-06T10:23:37', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '29651ea3-ce5c-428e-aa04-6675f44fa56b'	System	06 Feb 2021 16:23:49
User entered '06 Feb 2021 10:23:37'	System	06 Feb 2021 16:23:49

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 06:56:02



US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-02-13T14:18:45', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '290b7919-badf-4490-883b-398a7ea38d13' User entered 'No (N)'	System	13 Feb 2021 20:18:53
	System	13 Feb 2021 20:18:53

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-02-13T14:18:48', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '290b7919-badf-4490-883b-398a7ea38d13' User entered 'No (N)'	System	13 Feb 2021 20:18:53
	System	13 Feb 2021 20:18:53

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-02-13T14:18:50', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '290b7919-badf-4490-883b-398a7ea38d13' User entered '13 Feb 2021 14:18:50'	System	13 Feb 2021 20:18:53
	System	13 Feb 2021 20:18:53

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-02-21T06:32:21', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'fc5d152c-cdfe-43f0-ae9d-9c9267b3f278' User entered 'No (N)'	System	21 Feb 2021 12:32:29
	System	21 Feb 2021 12:32:29

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-02-21T06:32:23', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'fc5d152c-cdfe-43f0-ae9d-9c9267b3f278'	System	21 Feb 2021 12:32:29
User entered 'No (N)'	System	21 Feb 2021 12:32:29



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-02-21T06:32:26', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'fc5d152c-cdfe-43f0-ae9d-9c9267b3f278' User entered '21 Feb 2021 06:32:26'	System	21 Feb 2021 12:32:29

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-03-01T15:16:06-06:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'a217f4ed-a20e-4284-b25c-fe83f160db82'	System	01 Mar 2021 21:16:14
User entered 'No (N)'	System	01 Mar 2021 21:16:14

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-03-01T15:16:08-06:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'a217f4ed-a20e-4284-b25c-fe83f160db82'	System	01 Mar 2021 21:16:14
User entered 'No (N)'	System	01 Mar 2021 21:16:14

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-03-01T15:16:11-06:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'a217f4ed-a20e-4284-b25c-fe83f160db82' User entered '01 Mar 2021 15:16:11'	System	01 Mar 2021 21:16:14
	System	01 Mar 2021 21:16:14

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-03-09T12:34:35-06:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '906800c2-6c95-43ab-bf72-c85b935234ec' User entered 'No (N)'	System	09 Mar 2021 18:34:46
	System	09 Mar 2021 18:34:46

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-03-09T12:34:38-06:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '906800c2-6c95-43ab-bf72-c85b935234ec'	System	09 Mar 2021 18:34:46
User entered 'No (N)'	System	09 Mar 2021 18:34:46

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-03-09T12:34:41-06:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '906800c2-6c95-43ab-bf72-c85b935234ec' User entered '09 Mar 2021 12:34:41'	System	09 Mar 2021 18:34:46
	System	09 Mar 2021 18:34:46

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-03-15T05:12:32-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'af55734a-245a-4e9b-81d6-6ba3932b5d11' User entered 'Yes (Y)'	System	15 Mar 2021 10:13:16
	System	15 Mar 2021 10:13:16

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-03-15T05:12:37-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'af55734a-245a-4e9b-81d6-6ba3932b5d11' User entered 'No (N)'	System	15 Mar 2021 10:13:16
	System	15 Mar 2021 10:13:16

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-03-15T05:12:42-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'af55734a-245a-4e9b-81d6-6ba3932b5d11' User entered 'No (N)'	System	15 Mar 2021 10:13:16
	System	15 Mar 2021 10:13:16

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-03-15T05:12:57-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'af55734a-245a-4e9b-81d6-6ba3932b5d11' User entered 'Yes (Y)'	System	15 Mar 2021 10:13:16
	System	15 Mar 2021 10:13:16

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-03-15T05:13:02-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'af55734a-245a-4e9b-81d6-6ba3932b5d11'	System	15 Mar 2021 10:13:16
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Mar 2021 10:13:16

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-03-15T05:13:05-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'af55734a-245a-4e9b-81d6-6ba3932b5d11' User entered '15 Mar 2021 05:13:05'	System	15 Mar 2021 10:13:16
	System	15 Mar 2021 10:13:16

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 06:56:02

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-03-20T19:29:42-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '027f7363-ebe1-44b7-a229-82697938ae4a' User entered 'No (N)'	System	21 Mar 2021 00:29:55
	System	21 Mar 2021 00:29:55

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-03-20T19:29:47-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '027f7363-ebe1-44b7-a229-82697938ae4a' User entered 'No (N)'	System	21 Mar 2021 00:29:55
	System	21 Mar 2021 00:29:55

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-03-20T19:29:50-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '027f7363-eb1-44b7-a229-82697938ae4a' User entered '20 Mar 2021 19:29:50'	System	21 Mar 2021 00:29:55

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-03-27T09:37:48-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'c2444f56-a591-4e55-b26d-8107b9bae69a' User entered 'Yes (Y)'	System	27 Mar 2021 14:38:26
	System	27 Mar 2021 14:38:26



US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-03-27T09:37:53-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'c2444f56-a591-4e55-b26d-8107b9bae69a' User entered 'No (N)'	System	27 Mar 2021 14:38:26

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-03-27T09:37:59-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'c2444f56-a591-4e55-b26d-8107b9bae69a' User entered 'No (N)'	System	27 Mar 2021 14:38:26

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-03-27T09:38:08-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'c2444f56-a591-4e55-b26d-8107b9bae69a' User entered 'Yes (Y)'	System	27 Mar 2021 14:38:26

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-03-27T09:38:12-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'c2444f56-a591-4e55-b26d-8107b9bae69a'	System	27 Mar 2021 14:38:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Mar 2021 14:38:26

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-03-27T09:38:16-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'c2444f56-a591-4e55-b26d-8107b9bae69a' User entered '27 Mar 2021 09:38:16'	System	27 Mar 2021 14:38:26
	System	27 Mar 2021 14:38:26

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-04-07T09:18:00-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '6898acd7-5c3e-4312-b577-016ba3f3e6b0' User entered 'Yes (Y)'	System	07 Apr 2021 14:18:33
	System	07 Apr 2021 14:18:33

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-04-07T09:18:03-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '6898acd7-5c3e-4312-b577-016ba3f3e6b0' User entered 'No (N)'	System	07 Apr 2021 14:18:33

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-04-07T09:18:06-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '6898acd7-5c3e-4312-b577-016ba3f3e6b0' User entered 'No (N)'	System	07 Apr 2021 14:18:33

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-04-07T09:18:15-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '6898acd7-5c3e-4312-b577-016ba3f3e6b0' User entered 'Yes (Y)'	System	07 Apr 2021 14:18:33

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-04-07T09:18:18-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '6898acd7-5c3e-4312-b577-016ba3f3e6b0'	System	07 Apr 2021 14:18:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Apr 2021 14:18:33

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-04-07T09:18:21-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '6898acd7-5c3e-4312-b577-016ba3f3e6b0' User entered '07 Apr 2021 09:18:21'	System	07 Apr 2021 14:18:33
	System	07 Apr 2021 14:18:33

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-04-12T12:00:27-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '157db08f-42b0-4d55-a600-1bec3f30c409'	System	14 Apr 2021 15:29:03
User entered 'No (N)'	System	14 Apr 2021 15:29:03

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-04-12T12:00:29-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '157db08f-42b0-4d55-a600-1bec3f30c409'	System	14 Apr 2021 15:29:03
User entered 'No (N)'	System	14 Apr 2021 15:29:03

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-04-12T12:00:33-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '157db08f-42b0-4d55-a600-1bec3f30c409' User entered '12 Apr 2021 12:00:33'	System	14 Apr 2021 15:29:03

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-04-19T12:00:46-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'ce18a953-87b5-4b60-a7a9-7588f865048c' User entered 'No (N)'	System	19 Apr 2021 17:01:48



US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-04-19T12:00:47-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'ce18a953-87b5-4b60-a7a9-7588f865048c' User entered 'No (N)'	System	19 Apr 2021 17:01:48

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-04-19T12:00:52-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'ce18a953-87b5-4b60-a7a9-7588f865048c' User entered '19 Apr 2021 12:00:52'	System	19 Apr 2021 17:01:48
	System	19 Apr 2021 17:01:48

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-04-24T08:02:42-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '58a90f90-cfd3-4c26-924c-2264609eeec1' User entered 'No (N)'	System	24 Apr 2021 13:02:49
	System	24 Apr 2021 13:02:49

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-04-24T08:02:44-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '58a90f90-cfd3-4c26-924c-2264609eeec1' User entered 'No (N)'	System	24 Apr 2021 13:02:49

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-04-24T08:02:47-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '58a90f90-cfd3-4c26-924c-2264609eeec1' User entered '24 Apr 2021 08:02:47'	System	24 Apr 2021 13:02:49
	System	24 Apr 2021 13:02:49



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-05-03T12:00:31-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'f885ab43-ddfa-4b20-b886-f86165b2ce47'	System	03 May 2021 17:01:47
User entered 'No (N)'	System	03 May 2021 17:01:47

US3292172

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:26:50

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-05-03T12:00:34-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'f885ab43-ddfa-4b20-b886-f86165b2ce47'	System	03 May 2021 17:01:47
User entered 'No (N)'	System	03 May 2021 17:01:47

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-05-03T12:00:37-05:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: 'f885ab43-ddfa-4b20-b886-f86165b2ce47'	System	03 May 2021 17:01:47
User entered '03 May 2021 12:00:37'	System	03 May 2021 17:01:47

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 06:56:02



**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 06:56:02

**US3292172**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:26:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:02
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 06:56:02

US3292172

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:26:50**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:51:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-03-01T15:16:21-06:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '5d900599-45b2-408f-b269-2491fd425884'	System	01 Mar 2021 21:16:27
User entered 'No (N)'	System	01 Mar 2021 21:16:27

US3292172

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:26:50

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:51:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB78CE5D-DCF8-4241-AE6A-BED7D933DD1C)', Time: '2021-03-01T15:16:25-06:00', User OID: 'PatientReportedOutcome (US3292172)', ODM File OID: '5d900599-45b2-408f-b269-2491fd425884' User entered '01 Mar 2021 15:16:25'	System	01 Mar 2021 21:16:27
	System	01 Mar 2021 21:16:27

US3292172

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 17:13:02

US3292172

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '6 Nov 2020'	(b) (4), (b) (6)	15 Dec 2020 17:13:02



US3292172

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	15 Dec 2020 17:13:02

US3292172

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	(b) (4) System	15 Dec 2020 17:13:33
Please review and reconcile.' (Site from System).		
User entered '3 attempted with no answer' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 17:13:33
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System	15 Dec 2020 17:13:02
Please review and reconcile.' (Site from System).		
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 17:13:02

US3292172

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 17:13:40

US3292172

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:30
User entered 'l'	System	15 Dec 2020 17:13:40

**US3292172**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:26:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:57:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 17:14:09

**US3292172**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:26:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:57:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '12 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 17:14:09

**US3292172**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:26:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:57:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Dec 2020 17:14:09

US3292172

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:57:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 17:14:09



US3292172

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:57:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 17:14:16

**US3292172**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:26:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:57:56
User entered 'l'	System	15 Dec 2020 17:14:16

US3292172

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:57:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	11 Jan 2021 18:30:23

US3292172

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:57:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '8 Jan 2021'	(b) (4) Gerardo Pena (b) (4)	11 Jan 2021 18:30:23

US3292172

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:57:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Gerardo Pena (b) (4)	11 Jan 2021 18:30:23

US3292172

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:57:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'called patient three times; no answer.'	(b) (4) Gerardo Pena (b) (4)	11 Jan 2021 18:30:23

US3292172

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:57:56
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	11 Jan 2021 18:30:26

US3292172

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:57:56
User entered 'l'	System	11 Jan 2021 18:30:26



**US3292172**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:26:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:58:01
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 15:58:49

**US3292172**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:26:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:58:01
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '8 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 15:58:49

US3292172

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:58:01
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Feb 2021 15:58:49

US3292172

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:58:01
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 15:58:49

US3292172

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:58:01
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 15:58:54

US3292172

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:58:01
User entered 'l'	System	09 Feb 2021 15:58:54

US3292172

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:26:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Mar 2021 19:12:24

US3292172

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:26:50

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered '8 Mar 2021'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 19:12:24



US3292172

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:26:50

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Mar 2021 19:12:24

US3292172

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:26:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'VISIT4'	System	08 Mar 2021 19:12:24

US3292172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	31 Mar 2021 19:36:56

US3292172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4) Gerardo Pena (b) (4)	31 Mar 2021 19:36:56

US3292172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4) Gerardo Pena (b) (4)	31 Mar 2021 19:36:56

US3292172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered empty.	System	31 Mar 2021 19:36:56

US3292172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	31 Mar 2021 19:36:56

US3292172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	31 Mar 2021 19:36:56



US3292172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4) Gerardo Pena (b) (4)	31 Mar 2021 19:36:56

US3292172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4) Gerardo Pena (b) (4)	31 Mar 2021 19:36:56

US3292172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered empty.	System	31 Mar 2021 19:36:56

US3292172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4) Gerardo Pena (b) (4)	31 Mar 2021 19:36:56

US3292172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered empty.	System	31 Mar 2021 19:36:56

US3292172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4) Gerardo Pena (b) (4)	31 Mar 2021 19:36:56

US3292172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered empty.	System	31 Mar 2021 19:36:56

US3292172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4) Gerardo Pena (b) (4)	31 Mar 2021 19:36:56



US3292172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered empty.	System	31 Mar 2021 19:36:56

US3292172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56

US3292172

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:26:50

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56

US3292172

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:26:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'No (N)'	(b) (4), (b) (6)	08 Mar 2021 19:15:05

**US3292172**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:26:50**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 19:15:05

US3292172

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Mar 2021 19:15:28

US3292172

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered '8 Mar 2021'	(b) (4), (b) (6)	08 Mar 2021 19:15:28

US3292172

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered '09:49'	(b) (4), (b) (6)	08 Mar 2021 19:15:28



US3292172

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered '8 Mar 2021 09:49'	System	08 Mar 2021 19:15:28

US3292172

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Mar 2021 19:15:33

US3292172

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:56
User entered 'l'	System	08 Mar 2021 19:15:33

**US3292172**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:26:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 19:52:16

US3292172

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered '7 Apr 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 19:52:16

US3292172

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 19:52:16

US3292172

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:26:50

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 19:52:16

US3292172

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:26:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 19:52:28



**US3292172**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:26:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Apr 2021 19:52:28

US3292172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:26:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	31 Mar 2021 13:23:23

US3292172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:26:50

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	31 Mar 2021 13:23:23

US3292172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:26:50

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	31 Mar 2021 13:23:23

**US3292172**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:26:50**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'UNBLND_DECIDE'	System	31 Mar 2021 13:23:23

US3292172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:26:50

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User closed query 'Per CDM: Per sponsor review, the date of updated informed consent' and 'N/A - Subject Unblinded under Amendment 5 and Discontinued from Study' cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 15:17:45
Query 'Per CDM: Per sponsor review, the date of updated informed consent' and 'N/A - Subject Unblinded under Amendment 5 and Discontinued from Study' cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box' answered with 'Updated ' (Site from DM).		12 Apr 2021 02:26:32
User entered '8 Mar 2021' reason for change: Data Entry Error		12 Apr 2021 02:26:01
User opened query 'Per CDM: Per sponsor review, the date of updated informed consent' and 'N/A - Subject Unblinded under Amendment 5 and Discontinued from Study' cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box' (Site from DM).		07 Apr 2021 15:23:24
User entered empty.	Gerardo Pena (b) (4)	31 Mar 2021 13:23:38

US3292172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:26:50

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	31 Mar 2021 13:23:38

US3292172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:26:50

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	31 Mar 2021 13:23:38



US3292172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:26:50

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User closed query 'PER CDM: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' (Site from DM).	(b) (4)	12 Apr 2021 15:17:47
Query 'PER CDM: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' answered with 'Updated ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 02:27:37
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error		12 Apr 2021 02:26:01
User opened query 'PER CDM: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' (Site from DM).		08 Apr 2021 13:36:32
User entered 'Amendment 5 (Amendment 5)'	Gerardo Pena (b) (4) (b) (4)	31 Mar 2021 13:23:38

US3292172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:26:50

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4), (b) (6)	12 Apr 2021 15:17:49
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'Okay as is ' (Site from System).		12 Apr 2021 02:27:06
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	12 Apr 2021 02:26:01
User entered '15 Jan 2021'	Gerardo Pena (b) (4)	31 Mar 2021 13:23:38

US3292172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:26:50

[Participant randomization assignment](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	31 Mar 2021 13:23:38

US3292172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:26:50

[Actual Dose 1](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	31 Mar 2021 13:23:38

US3292172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:26:50

[Actual Dose 2](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	31 Mar 2021 13:23:38

US3292172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:26:50

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	31 Mar 2021 13:23:38

**US3292172**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:26:50**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 13:23:38

**US3292172**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:26:50**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 13:23:38



US3292172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	31 Mar 2021 13:23:42

US3292172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	31 Mar 2021 13:23:42

US3292172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:26:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	31 Mar 2021 13:23:42

**US3292172**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:26:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 13:23:42

US3292172

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:26:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	31 Mar 2021 13:23:45

US3292172

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:26:50**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	31 Mar 2021 13:23:45

US3292172

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:26:50**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	31 Mar 2021 13:23:45

**US3292172**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:26:50**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 13:23:45



US3292172

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:26:50

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 229 (27MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:25:55
Query 'Per DM CLR: Per Safety Follow Up Diary Day 229 (27MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'Patient had stomach bug no medicine or nothing medically attended ' (Site from DM).		14 Apr 2021 01:22:45
User entered 'No (N)' reason for change: New Information		14 Apr 2021 01:22:09
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 229 (27MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).		04 Apr 2021 07:53:43
Signature has been broken.	Gerardo Pena (b) (4)	16 Mar 2021 16:43:20
User entered 'Yes (Y)' reason for change: New Information	Gerardo Pena (b) (4)	16 Mar 2021 16:43:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43

US3292172

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:26:50

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Dawn Killian (b) (4) (b) (4)	03 Feb 2021 22:14:21

US3292172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:36:14
User entered 'USA-US072-2021-mRNA-1273-P301000020'	System	27 Apr 2021 15:36:06
User entered 'New'	(b) (4), (b) (6)	27 Apr 2021 15:36:06

US3292172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female malignant and unspecified, HLT: Uterine neoplasms malignant NEC, PT: Uterine cancer, LLT: Uterine cancer - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Mar 2021 16:46:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 16:46:59
Data point term sent to Coder	System	16 Mar 2021 16:45:27
User entered 'uterine cancer'	Gerardo Pena (b) (4)	16 Mar 2021 16:45:18

US3292172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	16 Mar 2021 16:45:18

US3292172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Mar 2021 16:45:18

US3292172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Mar 2021 16:45:18

US3292172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered '19 Feb 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Mar 2021 16:45:18



US3292172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Mar 2021 16:45:18

**US3292172**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:26:50**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 16:45:18

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
	(b) (4)	
Signature has been broken.	Nathan Cortez (b) (4)	26 Apr 2021 19:20:52
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Nathan Cortez (b) (4)	26 Apr 2021 19:20:52
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
	(b) (4)	
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	16 Mar 2021 16:45:18
	(b) (4)	

US3292172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) System	26 Apr 2021 19:23:01
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	26 Apr 2021 19:23:01
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	26 Apr 2021 19:22:33
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	26 Apr 2021 19:22:33
Signature has been broken.	Nathan Cortez (b) (4)	26 Apr 2021 19:22:33
User entered '07 Apr 2021' reason for change: Data Entry Error	Nathan Cortez (b) (4)	26 Apr 2021 19:22:33
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	26 Apr 2021 19:20:52
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4) Gerardo Pena (b) (4)	16 Mar 2021 16:45:18

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Mar 2021 16:45:18

**US3292172**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:26:50**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 16:45:18

US3292172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Signature has been broken.	(b) (4)	
	Nathan Cortez (b) (4)	26 Apr 2021 19:18:37
User entered 'Grade 3/Severe (Grade 3/Severe)'	Nathan Cortez (b) (4)	26 Apr 2021 19:18:37
reason for change: New Information		
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Gerardo Pena (b) (4)	16 Mar 2021 16:45:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
User closed query 'Per MM: please confirm seriousness assessment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Apr 2021 14:02:20
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	26 Apr 2021 19:20:52
Query 'Per MM: please confirm seriousness assessment. ' answered with 'Updated to SAE' (Site from DM).	Nathan Cortez (b) (4)	26 Apr 2021 19:20:08
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	26 Apr 2021 19:18:37
Signature has been broken.	Nathan Cortez (b) (4)	26 Apr 2021 19:18:37
User entered 'Yes (Y)' reason for change: New Information	Nathan Cortez (b) (4)	26 Apr 2021 19:18:37
User opened query 'Per MM: please confirm seriousness assessment. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 00:17:43
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Mar 2021 16:45:18



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Mar 2021 16:45:18

US3292172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Mar 2021 16:45:18

US3292172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Mar 2021 16:45:18

US3292172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Mar 2021 16:45:18

US3292172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4) Gerardo Pena (b) (4)	16 Mar 2021 16:45:18

US3292172

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Mar 2021 16:45:18

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Mar 2021 16:45:18

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Mar 2021 16:45:18



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Mar 2021 16:45:18

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Signature has been broken.	(b) (4)	
	Nathan Cortez (b) (4)	26 Apr 2021 19:20:52
User entered '1' reason for change: New Information	(b) (4)	
	Nathan Cortez (b) (4)	26 Apr 2021 19:20:52
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered '0'	(b) (4)	
	Gerardo Pena (b) (4)	16 Mar 2021 16:45:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Mar 2021 21:06:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Mar 2021 21:06:23
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	18 Mar 2021 21:06:23
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Mar 2021 16:45:18
User entered empty.	Gerardo Pena (b) (4)	16 Mar 2021 16:45:18

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Mar 2021 21:06:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Mar 2021 21:06:23
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	18 Mar 2021 21:06:23
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Mar 2021 16:45:18
User entered empty.	Gerardo Pena (b) (4)	16 Mar 2021 16:45:18

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'None (NONE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Mar 2021 16:45:18

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System). Signature has been broken.	(b) (4)	26 Apr 2021 19:20:52
	Nathan Cortez (b) (4)	26 Apr 2021 19:20:52
User entered '0' reason for change: Data Entry Error	Nathan Cortez (b) (4)	26 Apr 2021 19:20:52
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System). User signature succeeded.	System	26 Apr 2021 19:18:37
	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered '1'	(b) (4)	
	Gerardo Pena (b) (4)	16 Mar 2021 16:45:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Mar 2021 16:45:18

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Signature has been broken.	(b) (4)	
	Nathan Cortez (b) (4)	26 Apr 2021 19:18:37
User entered '1' reason for change: New Information	(b) (4)	
	Nathan Cortez (b) (4)	26 Apr 2021 19:18:37
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
	(b) (4)	
User entered '0'	Gerardo Pena (b) (4)	16 Mar 2021 16:45:18
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Signature has been broken.	(b) (4)	
	Nathan Cortez (b) (4)	26 Apr 2021 19:23:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Nathan Cortez (b) (4)	26 Apr 2021 19:23:01
Data Entry Error		
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Gerardo Pena (b) (4)	16 Mar 2021 16:45:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Mar 2021 16:45:18

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:26:50

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Mar 2021 16:45:18

**US3292172**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:26:50**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Apr 2021 19:18:37
User entered '0'	System	16 Mar 2021 16:45:18

**US3292172**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:26:50**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Mar 2021 16:45:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:26:50

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:03
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:50
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 10:43:30
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.		16 Apr 2021 17:25:50
' answered with 'Updated ' (Site from DM).		
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).		03 Feb 2021 11:13:36
User entered 'Yes (Y)'		16 Aug 2020 03:04:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:26:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: CETIRIZINE HYDROCHLORIDE;PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC-D - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Aug 2020 03:06:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Aug 2020 03:06:21
Data point term sent to Coder	System	16 Aug 2020 03:05:10
User entered 'Zyrtec-D'	(b) (4), (b) (6)	16 Aug 2020 03:04:48

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:26:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:04:48



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:26:50**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Seasonal allergy'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:04:48

US3292172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:26:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 120/5).' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 11:51:52
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 120/5).' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	21 Sep 2020 18:10:56
User entered '120/5' reason for change: Data Entry Error	Dawn Killian (b) (4)	21 Sep 2020 18:10:02
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 120/5).' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 07:57:56
User entered '120'		16 Aug 2020 03:04:48

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:26:50**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:04:48

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:26:50**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:04:48

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:26:50**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:04:48

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:26:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:04:48

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:26:50**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:04:48

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:26:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:04:48



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:26:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
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)	
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)	16 Aug 2020 13:06:42
answered with 'Medication is ongoing, correct as entered' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 03:06:13
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	16 Aug 2020 03:04:48
User entered 'un UNK 2010'	(b) (4), (b) (6)	16 Aug 2020 03:04:48

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:26:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:04:48

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:26:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:04:48

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:26:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:04:48

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:26:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:04:48

**US3292172**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:26:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Aug 2020 03:04:48

**US3292172**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:26:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Aug 2020 03:04:48

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:26:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Aug 2020 03:04:48



US3292172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:26:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Aug 2020 03:06:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Aug 2020 03:06:22
Data point term sent to Coder	System	16 Aug 2020 03:06:10
User entered 'Tylenol'	(b) (4), (b) (6)	16 Aug 2020 03:05:47

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:26:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:05:47

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:26:50**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Headache'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:05:47

US3292172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:26:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '1000' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 21:37:01
User entered '500'		16 Aug 2020 03:05:47

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:26:50**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:05:47

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:26:50**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:05:47

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:26:50**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:05:47

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:26:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:05:47



US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:26:50**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:05:47

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:26:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:05:47

US3292172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:26:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
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)	
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)	16 Aug 2020 13:06:46
answered with 'Medication is ongoing, correct as entered' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 03:06:07
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	16 Aug 2020 03:05:47
User entered 'un UNK 1985'	(b) (4), (b) (6)	16 Aug 2020 03:05:47

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:26:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:05:47

US3292172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:26:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:05:47

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:26:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:05:47

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:26:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 03:05:47

**US3292172**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:26:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Aug 2020 03:05:47



US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:26:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Aug 2020 03:05:47

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:26:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Aug 2020 03:05:47

US3292172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:26:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Apr 2021 20:19:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 20:19:52
Data point term sent to Coder	System	08 Apr 2021 20:18:31
User entered 'tramadol'	(b) (4), (b) (6)	08 Apr 2021 20:17:48

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:26:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:17:48

**US3292172**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:26:50**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'pain'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:17:48

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:26:50**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered '50'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:17:48

US3292172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:26:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:17:48

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:26:50**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:17:48



US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:26:50**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:17:48

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:26:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:17:48

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:26:50**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:17:48

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:26:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:17:48

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:26:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered '5 Apr 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:17:48

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:26:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:17:48

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:26:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:17:48

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:26:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:17:48



US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:26:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:17:48

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:26:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 20:17:48

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:26:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 20:17:48

**US3292172**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:26:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 20:17:48

US3292172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:26:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Apr 2021 17:32:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 17:32:57
Data point term sent to Coder	System	16 Apr 2021 17:26:25
User entered 'Tylenol'	(b) (4), (b) (6)	16 Apr 2021 17:25:32

**US3292172**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:26:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Apr 2021 17:25:32

US3292172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:26:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:50
User entered 'Reactogenicity - pain at injection site'	(b) (4), (b) (6)	16 Apr 2021 17:25:32

**US3292172**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:26:50**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:50
User entered '500'	(b) (4), (b) (6)	16 Apr 2021 17:25:32



US3292172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:26:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:50
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:25:32

US3292172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:26:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:25:32

**US3292172**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:26:50**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:50
User entered 'as needed (PRN)'	(b) (4), (b) (6)	16 Apr 2021 17:25:32

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:26:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:25:32

**US3292172**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:26:50**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:50
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:25:32

**US3292172**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:26:50**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:25:32

**US3292172**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:26:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:50
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:25:32

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:26:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:50
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:25:32



**US3292172**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:26:50**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:50
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 17:25:32

**US3292172**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:26:50**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:50
User entered '11 Sep 2020'	(b) (4), (b) (6)	16 Apr 2021 17:25:32

US3292172

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:26:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:25:32

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:26:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
User entered empty.	System	16 Apr 2021 17:25:32

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:26:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
User entered empty.	System	16 Apr 2021 17:25:32

US3292172

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:26:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
User entered empty.	System	16 Apr 2021 17:25:32

US3292172

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:26:50

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
Signature has been broken.	(b) (4)	
	Gerardo Pena (b) (4)	16 Mar 2021 16:46:03
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Gerardo Pena (b) (4)	16 Mar 2021 16:46:03
	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:56:43
	(b) (4)	
User entered 'No (N)'	Dawn Killian (b) (4)	04 Feb 2021 16:32:15
	(b) (4)	

US3292172

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 16:26:50**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered '19 Feb 2021'	(b) (4) Gerardo Pena (b) (4)	16 Mar 2021 16:46:28



US3292172

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 16:26:50**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'pap smear'	(b) (4) Gerardo Pena (b) (4)	16 Mar 2021 16:46:28

US3292172

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 16:26:50**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Mar 2021 16:46:28

US3292172

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 16:26:50**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:00
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Mar 2021 16:46:28

US3292172

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 16:26:50**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:50
User entered '5 Apr 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:21:43

US3292172

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 16:26:50**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:50
User entered 'Total Hysterectomy'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:21:43

US3292172

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 16:26:50**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:50
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:21:43

US3292172

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 16:26:50**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:47:50
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:21:43

**US3292172**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:26:50**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:37:30
User entered 'USA-US072-2021-MRNA-1273-P301000020'	System	27 Apr 2021 15:36:06



**US3292172**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:26:50**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:37:30
User entered 'Yes (Y)'	System	27 Apr 2021 15:36:06

**US3292172**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:26:50**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:37:30
User entered 'No (N)'	System	27 Apr 2021 15:36:06

US3292172

Folder: SAE USA-US072-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:37:30
User entered 'No (N)'	System	27 Apr 2021 15:36:06

**US3292172**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:26:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:37:30
User entered 'No (N)'	System	27 Apr 2021 15:36:06

US3292172

Folder: SAE USA-US072-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:37:30
User entered 'No (N)'	System	27 Apr 2021 15:36:06

**US3292172**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:26:50**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:37:30
User entered 'No (N)'	System	27 Apr 2021 15:36:06

**US3292172**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:26:50**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:37:30
User entered 'Yes (Y)'	System	27 Apr 2021 15:36:06

US3292172

Folder: SAE USA-US072-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:37:30
User entered 'Douglas'	System	27 Apr 2021 15:36:06



US3292172

Folder: SAE USA-US072-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:37:30
User entered 'Denham'	System	27 Apr 2021 15:36:06

**US3292172**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:26:50**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:37:30
User entered '7940 Floyd Curl Drive'	System	27 Apr 2021 15:36:06

**US3292172**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:26:50**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:37:30
User entered 'San Antonio'	System	27 Apr 2021 15:36:06

**US3292172**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:26:50**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:37:30
User entered '78229'	System	27 Apr 2021 15:36:06

US3292172

Folder: SAE USA-US072-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
User entered 'US'	(b) (4) System	27 Apr 2021 15:38:13

**US3292172**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:26:50**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Apr 2021 15:38:13

**US3292172**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:26:50**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:37:30
User entered 'USA-US072-2021-MRNA-1273-P301000020'	System	27 Apr 2021 15:36:06

**US3292172**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:26:50**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:37:30
User entered 'Yes (Y)'	System	27 Apr 2021 15:36:06



**US3292172**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:26:50**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:37:30
User entered 'No (N)'	System	27 Apr 2021 15:36:06

**US3292172**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:26:50**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:37:30
User entered 'No (N)'	System	27 Apr 2021 15:36:06

US3292172

Folder: SAE USA-US072-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:37:30
User entered 'No (N)'	System	27 Apr 2021 15:36:06

US3292172

Folder: SAE USA-US072-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:37:30
User entered 'No (N)'	System	27 Apr 2021 15:36:06

**US3292172**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:26:50**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:37:30
User entered 'No (N)'	System	27 Apr 2021 15:36:06

US3292172

Folder: SAE USA-US072-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:37:30
User entered 'Yes (Y)'	System	27 Apr 2021 15:36:06

US3292172

Folder: SAE USA-US072-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:37:30
User entered 'Douglas'	System	27 Apr 2021 15:36:06

US3292172

Folder: SAE USA-US072-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:37:30
User entered 'Denham'	System	27 Apr 2021 15:36:06



**US3292172**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:26:50**

**Site Address: [Street](#)**

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:37:30
User entered '7940 Floyd Curl Drive'	System	27 Apr 2021 15:36:06

**US3292172**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:26:50**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:37:30
User entered 'San Antonio'	System	27 Apr 2021 15:36:06

**US3292172**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:26:50**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:37:30
User entered '78229'	System	27 Apr 2021 15:36:06

US3292172

Folder: SAE USA-US072-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:26:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
User entered 'US'	(b) (4) System	27 Apr 2021 15:38:13

**US3292172**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000020**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:26:50**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Apr 2021 15:38:13

**US3292172**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000020**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 16:26:50**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
User entered '27/Apr/2021 08:38'	(b) (4) System	27 Apr 2021 15:38:13

US3292172

Folder: SAE USA-US072-2021-MRNA-1273-P301000020

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:26:50

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:41
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:38:13
User entered '0'		27 Apr 2021 15:37:46